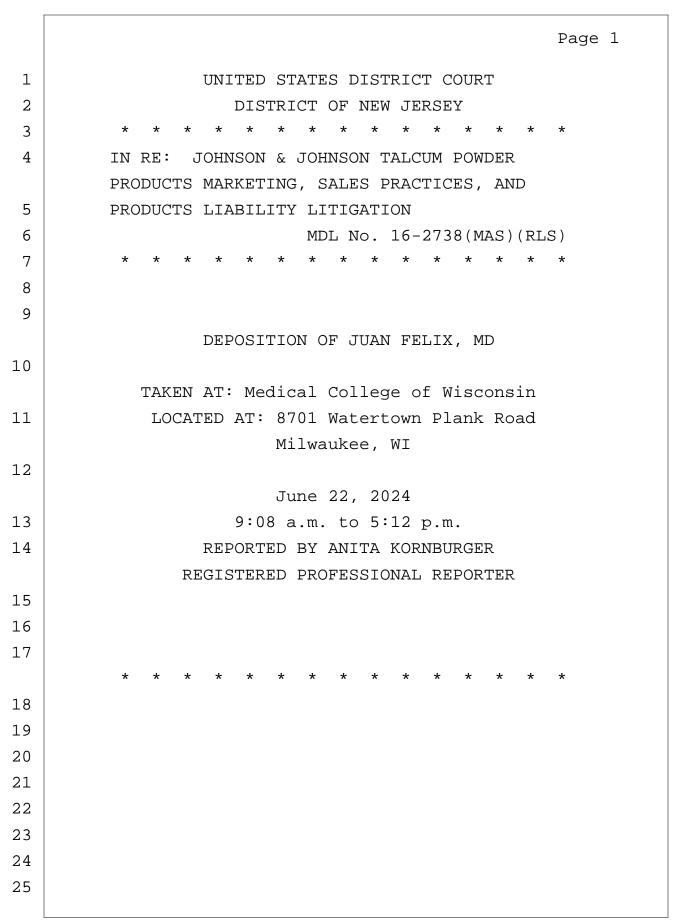
Exhibit 2



D 2	D 4				
Page 2 1 APPEARANCES	Page 4				
2 BEASLEY ALLEN, by	1 TRANSCRIPT OF PROCEEDINGS				
Mr. David Dearing	2 JUAN FELIX, MD, called as a witness				
3 218 Commerce St	3 herein, having been first duly sworn on oath,				
Montgomery, AL, 36104 4 334-269-2343	4 was examined and testified as follows:				
david.dearing@beasleyallen.com	5 EXAMINATION				
5 Appearing on behalf of the Plaintiffs.	6 BY MR. DEARING:				
6 SHOOK, HARDY & BACON, by	7 Q. Good morning, Dr. Felix.				
Mr. Mark Hegarty 7 2555 Grand Boulevard	_				
Kansas City, MO 64108	8 A. Good morning.				
8 816.474.6550	9 Q. For efficiency, as I just explained off				
mhegarty@shb.com	10 the record, I'm going to start with just some				
9 Appearing on behalf of the Defendants.10 REILLY, MCDEVITT HENRICH, by	11 general questions that I believe apply to all seve				
Mr. Paul Smyth	12 cases. And then I'll eventually move into more				
11 3 Executive Campus, Suite 310	13 case-specific questions. But of course I'll tell				
Cherry Hill, NJ 08002	14 you when I'm transitioning to something case				
12 856.317.7180 psmyth@rmh-law.com					
13 Appearing by Zoom on behalf of the Defendants.	15 specific so that no one is confused.				
14	And when I just generally refer to				
INDEX 15	17 these cases or these seven cases, I'm referring to				
16 Examination by Page	18 Carl, Balderrama, Rausa, Converse, Judkins,				
17 Mr. Dearing	19 Gallardo, and Bondurant, those seven.				
Mr. Hegarty	These initial questions, like I said,				
18 Mr. Dearing	21 are general in nature. But if you think you need				
20	· ·				
21	22 to make a distinction with regard to your answer to				
22	23 a specific case, please tell me you're making the				
23 24	24 distinction or you're referring to a specific case.				
25	25 Otherwise I'm going to presume that your answers				
Page 3	Page 5				
1 EXHIBITS	1 cover all of them.				
Page	2 A. Very well.				
Exhibit No. Description Identified 3	3 Q. Okay. So let's start with the deposition				
1 Anatomic diagram of the					
4 female reproductive tract 78	4 itself. How much time did you spend preparing for				
5 2 Cross-section of the female	5 the deposition?				
reproductive tract 79	6 A. Probably in the neighborhood of ten to				
6 3 Study by Dr. Sandra McDonald 85	7 twelve hours.				
7	8 Q. And that covers all seven				
	8 Q. And that covers all seven				
4 Invoices pertaining to Carl 160	_				
4 Invoices pertaining to Carl 160	9 A. Yes.				
4 Invoices pertaining to Carl 160 8 5 Providence Holy Cross Medical	9 A. Yes. 10 Q clients?				
4 Invoices pertaining to Carl 160 8 5 Providence Holy Cross Medical 9 Center pathology report 167	9 A. Yes. 10 Q clients? 11 A. Yes.				
4 Invoices pertaining to Carl 160 8 5 Providence Holy Cross Medical 9 Center pathology report 167 10 6 Brandi Carl report 207	9 A. Yes. 10 Q clients? 11 A. Yes. 12 Q. Was some of that time meeting with				
4 Invoices pertaining to Carl 160 8 5 Providence Holy Cross Medical 9 Center pathology report 167 10 6 Brandi Carl report 207 11 7 Balderrama report 207	9 A. Yes. 10 Q clients? 11 A. Yes.				
4 Invoices pertaining to Carl 160 8	9 A. Yes. 10 Q clients? 11 A. Yes. 12 Q. Was some of that time meeting with				
4 Invoices pertaining to Carl 160 8 5 Providence Holy Cross Medical 9 Center pathology report 167 10 6 Brandi Carl report 207 11 7 Balderrama report 207 12 8 Rausa report 207 13 9 Converse report 207 14 10 Gallardo report 207	 9 A. Yes. 10 Q clients? 11 A. Yes. 12 Q. Was some of that time meeting with 13 lawyers? 14 A. The meeting with attorneys were in 				
4 Invoices pertaining to Carl 160 8 5 Providence Holy Cross Medical 9 Center pathology report 167 10 6 Brandi Carl report 207 11 7 Balderrama report 207 12 8 Rausa report 207 13 9 Converse report 207 14 10 Gallardo report 207 15 11 Judkins report	9 A. Yes. 10 Q clients? 11 A. Yes. 12 Q. Was some of that time meeting with 13 lawyers? 14 A. The meeting with attorneys were in 15 addition to the twelve hours.				
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4 Invoices pertaining to Carl 160 8 5 Providence Holy Cross Medical 9 Center pathology report 167 10 6 Brandi Carl report 207 11 7 Balderrama report 207 12 8 Rausa report 207 13 9 Converse report 207 14 10 Gallardo report 207 15 11 Judkins report 207 16 12 Bondurant report 207 17 13 Ms. Gallardo's surgical pathology	9 A. Yes. 10 Q clients? 11 A. Yes. 12 Q. Was some of that time meeting with 13 lawyers? 14 A. The meeting with attorneys were in 15 addition to the twelve hours. 16 Q. Okay. How many hours did you spend 17 meeting with attorneys to prepare for the				
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4 Invoices pertaining to Carl	9 A. Yes. 10 Q clients? 11 A. Yes. 12 Q. Was some of that time meeting with 13 lawyers? 14 A. The meeting with attorneys were in 15 addition to the twelve hours. 16 Q. Okay. How many hours did you spend 17 meeting with attorneys to prepare for the 18 deposition? 19 A. Probably a total of three hours.				
4 Invoices pertaining to Carl	9 A. Yes. 10 Q clients? 11 A. Yes. 12 Q. Was some of that time meeting with 13 lawyers? 14 A. The meeting with attorneys were in 15 addition to the twelve hours. 16 Q. Okay. How many hours did you spend 17 meeting with attorneys to prepare for the 18 deposition?				
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D (D 0
Page 6	Page 8 1 MR. HEGARTY: We provided three invoices.
1 Q. Right. 2 A. Save me time.	_
	2 MR. DEARING: They were all for the Carl
3 Q. We do that. We're big on binders.	3 case, though.
4 A. Yeah.	4 MR. HEGARTY: I can look at them just to
5 Q. Okay. Did they provide you any medical	5 confirm that, but you probably have copies
6 records or did you already have them?	6 MR. DEARING: We're going to go over
7 A. I had the medical records for all seven	7 them.
8 of these patients.	8 MR. HEGARTY: Okay.
9 Q. Okay. What about any studies? Did they	9 MR. DEARING: I was just curious why
10 provide you with any studies in preparation for	10 there weren't
11 today?	MR. HEGARTY: That's because they have
12 A. They did not. Most of the studies that I	12 not been created.
13 relied on either were provided to me by the	13 MR. DEARING: Okay.
14 attorneys many years ago or were the product of	14 BY MR. DEARING:
15 literature searches on my part.	15 Q. So to be clear, you've never billed for
16 Q. Did they at some point show you the	16 that time in the other MDL cases?
17 notice of deposition that was served in this case?	17 A. I have not yet, no.
18 A. Yes.	Q. Okay. And Balderrama has been around as
19 Q. In that notice we requested that you	19 long as Carl. Have you invoiced anything in that
20 provide several things, namely, invoices for each	20 case?
21 case, but we were only provided invoices in one	A. Not that I'm aware of, no.
22 case, in the Carl case. Is that because you don't	Q. Ever in the last seven, eight years since
23 have them or were unable to produce them or what?	23 it's been created?
24 A. So I don't personally invoice. My wife	24 A. Correct.
1	
1 25 keeps tally of my hours. And she invoices. And	25 O. So I've deposed you a few times in the
25 keeps tally of my hours. And she invoices. And	25 Q. So I've deposed you a few times in the
Page 7	Page 9
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Page 7 1 these cases are so some of these cases are so 2 old that when I asked her, hey, did you prepare 3 invoices, she said it would take me a week to be 4 able to invoice these cases. And I said, well, 5 don't worry about it. We'll do it after the 6 deposition. 7 Q. Okay. What's your wife's name? 8 A. Betsy. B-E-T-S-Y. 9 Q. Felix? 10 A. Yes. 11 Q. So are you saying that you just haven't 12 issued any invoices in the last few years or so in 13 these cases except for Carl? 14 A. That's correct. 15 MR. DEARING: And Mark, we would still 16 like to get the old invoices at some point. 17 MR. HEGARTY: Yeah, we were intending to 18 provided all invoices for the seven cases. We 19 provided those that have been created. 20 MR. DEARING: The only 21 MR. HEGARTY: There are no others that	Page 9 1 past, and I'm going to try not to go back over 2 things I've already deposed you on. But let me 3 just ask you now, since I haven't deposed you in a 4 while, how much time do you spend actually caring 5 for patients, in other words, reviewing surgical 6 slides? 7 A. I spend probably eight hours a day doing 8 patient care. 9 Q. And as a pathologist, do you actually 10 meet with patients or is that mostly done outside 11 their presence, the work you do? 12 A. Since I have been at Medical College of 13 Wisconsin, I have only interacted once or twice 14 with a patient in a role as a cytologist that's 15 C-Y-T-O doing a fine needle aspiration. In my 16 prior job I used to interact with patients on a 17 daily basis. But here at MCW, that ceased. 18 Q. Okay. And how long have you been here at 19 MCW? 20 A. Seven-and-a-half years. 21 Q. Are most of your interactions with other

25 invoices that we --

THE WITNESS: I think there are three

24 in my role as a chief of anatomic pathology, both

25 administratively and as a colleague, meaning

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Page 10

- 1 looking at cases that are difficult for them. But
- 2 I also interact with surgeons mostly in the
- 3 department of ob/gyn, but also in the department of
- 4 surgical oncology.
- 5 Q. Has the -- I'm sorry, your title is chief
- 6 of pathology?
- 7 A. Chief of anatomic pathology. Two
- 8 branches of pathology, anatomic and clinical.
- 9 Clinical pathology is laboratory medicine.
- 10 Q. Right.
- 11 A. That does all the blood work, urine,
- 12 fluids. And I did not train in that area. I
- 13 limited my training to the anatomic pathology.
- 14 Q. Does anatomic pathology include autopsy
- 15 service, that kind of thing?
- 16 A. Yes. I am actually the director of
- 17 autopsy at MCW right now.
- 18 Q. So does -- does an anatomical pathologist
- 19 do surgical pathology review --
- 20 A. Yes.

23

- Q. -- in cancer patients?
- 22 A. Yes.
- 24 are you actually reviewing slides on a day-to-day
- 25 basis from -- straight from the surgeon, or do you
 - Page 11
- 1 only review when another pathologist comes to you

Q. And as the chief of anatomical pathology,

- 2 and says hey, I need help with this?
- A. So currently I am the only
- 4 fellowship-trained ob/gyn trained pathologist at
- 5 MCW. So I review all of the ob/gyn pathology cases
- 6 that come into the laboratory every day.
- 7 Q. So you said you spend about eight hours a
- 8 day looking at slides; is that right?
- 9 A. Well, I also participate in the autopsy.
- 10 So, for example, yesterday we started an autopsy at
- 11 ten and finished at twelve. And prior to that I
- 12 was doing -- picking out slides from cases in the
- 13 past to send out to molecular -- molecular labs
- 14 such as Foundation or Caris. I have -- we have to
- 15 look through the case and pick the best slide to
- 16 send to those -- to those laboratories. And that
- 17 takes about an hour to an hour and a half every
- 18 day.
- 19 Q. What do those laboratories do?
- 20 A. They do next generation sequencing of the
- 21 tumors in order to provide information for possible
- 22 personalized therapies. Then after my autopsy, I
- 23 sat down with the fellow in ob/gyn pathology and
- 24 looked at all of the cases for the day. There were
- 25 about 45, 50 cases yesterday. So that took us to

1 about five o'clock.

- Q. Okay. About how much time is typical, if
- 3 there is such a thing, to look at the slides from
- 4 an ovarian cancer case to diagnose it?
- 5 A. Right. So it almost always takes between
- 6 20 and 40 minutes to go through the entire case.
- 7 Q. And as a rule you're not typically
- 8 polarizing those slides, are you?
- 9 A. As a general rule, I do not use polarized
- 10 microscopy to look at ovarian cancer, correct. Let
- 11 me modify my answer. In cases where there's very
- 12 extensive disease that's very obvious, it may take
- 13 as little as ten minutes.
- 14 Q. Okay.
- 15 A. Okay. Because you just put the slide on
- 16 and --
- 17 Q. You know it when you see it?
- 18 A. Yeah.
- 19 Q. Are you presently working on any
- 20 publications or projects that you intend to
- 21 publish?

24

- 22 A. Yes.
- Q. Can you tell me about those?
 - A. Yeah. Most -- most of them are in two
- 25 groups of topics. One of them is in the work that

- 1 I do for cervical cancer prevention in countries of
 - 2 low income. We have two manuscripts that are
 - 3 currently being prepared. One of them is a really
 - 4 revolutionary publication that will probably change
 - 5 the way we treat cervical cancer, resulting from
 - 6 clinical trials that we've done. So those are
 - 7 summaries of clinical trials in cervical cancer
 - 8 prevention.
 - 9 The other group of publications is in
 - 10 the field of COVID. When COVID hit in 2020, I was
 - 11 the only pathologist who agreed to do COVID
 - 12 autopsies. And I took the opportunity to start a
 - 13 biorepository of tissues. And I have -- I did
 - 14 about 80 COVID autopsies. The first 20 I obtained
 - 15 frozen tissue from most major organs.
 - So now I am collaborating with basic
 - 17 scientists. The closest collaboration that I have
 - 18 is with Ivor Benjamin, I-V-O-R, and we are looking
 - 19 at some -- and I won't lie to you, I don't know the
 - 20 name of the molecules -- but some molecules that
 - 21 are profibrotic, meaning they tend to increase the
 - 22 fibrosis in organs, using my samples.
 - So we've already published two
 - 24 articles in there -- in that topic. And I am
 - 25 listed in two grant applications for that. So

Page 14

- 1 those are the two major areas.
- Q. I'd love to spend some time picking your
- 3 brain about all that, but I need to move on. I
- 4 look forward to reading it.
- 5 So you're not presently working on any 6 projects for publication involving ovarian cancer?
- 7 A. I am not.
- 8 Q. Some time ago you and I got into a
- 9 lengthy discussion about cervical cancer. And I
- 10 believe you opined that the only cause of cervical
- 11 cancer is HPV; is that right?
- 12 A. By far the predominant cause of cervical
- 13 cancer is HPV. There are rare, non-HPV-associated
- 14 cervical cancers. Those are a very special type of
- 15 cervical cancer called gastric adenocarcinomas.
- 16 And they represent .1 percent of all cervical
- 17 cancers.
- 18 Q. Gastric meaning derived from the
- 19 digestion system?
- 20 A. No. It's a horrible name to have given
- 21 them. They used to be called adenoma malignum.
- 22 Then they changed the name to minimal deviation
- 23 adenocarcinomas. And then the WHO, in all their
- 24 wisdom, termed them gastric because some of the
- 25 mucin that is produced by these cancers were
- _ _
- Page 15
- 1 similar to the mucin in gastric adenocarcinomas.
- 2 But it confuses a lot of people, including
- 3 pathologists.
- 4 Q. It's probably the same person that named
- 5 endometrioid carcinoma, 'cause -- never mind.
- 6 Is it fair to say most of your
- 7 clinical research at this time involves cervical
- 8 cancer and the COVID work that you're doing?
- 9 A. Currently, yes.
- 10 Q. And has that been true for the past,
- 11 what, four, five years?
- 12 A. You're correct, yes.
- Q. In the past five years have you ever
- 14 given any kind of presentation that included the
- 15 topic of causes of ovarian cancer?
- 16 A. Yes. I teach medical students at the
- 17 Medical College of Wisconsin, and there's an annual
- 18 lecture on ovarian cancer in which I -- I outline
- 19 the major associations to ovarian cancer.
- Q. Is that a one-day lecture or multiple
- 21 days or --
- A. For ovarian cancer, it's a one-hour
- 23 lecture.
- Q. One hour.
- 25 A. Yeah.

- Q. Cover a lot of ground in one hour.
- 2 A. Yeah. They have been reducing the
- 3 didactic content of medical school to the point
- 4 that if you -- students relied only on what is
- 5 being taught in lecture, they would be lay people,
- 6 not doctors. But that is a personal opinion.
- 7 Q. I understand. Are those lectures ever
- 8 transcribed? Are they in written form anywhere?
- A. Yes. They are -- they are -- I created a
- 10 PowerPoint presentation that is -- that is
- 11 available to all the medical students through the
- 12 MCW website. I don't know whether it's available
- 13 to the public.
- 14 Q. Okay.
- 15 A. But, I mean, I could provide you with
- 16 that PowerPoint. Not all of the information that I
- 17 speak is in the slides, but --
- 18 Q. Right.
- 19 A. -- it's a -- it's a format for me to
- 20 follow.
- Q. Would it be fair to say that it's a
- 22 cursory review of ovarian cancer given the fact you
- 23 only have an hour to give it?
- 24 MR. HEGARTY: Objection to the form.
- 25 THE WITNESS: It is a -- it is an outline

Page 17

- 1 of ovarian cancers meant to guide the students'
- 2 search into ovarian cancer.
- 3 BY MR. DEARING:
- Q. And does the issue of -- is the issue of
- 5 genital talc use incorporated in that presentation
- 6 at all?

- A. It is not.
- 8 Q. Are there any environmental factors that
- 9 you include as risk factors for ovarian cancer?
- 10 A. Environmental, would that include
- 11 medications or hormones?
- 12 Q. Well, often when I see a list of risk
- 13 factors for ovarian cancer, it'll say environmental
- 14 exposures, and it's a very general term. But I
- 15 would open it as general as you want to make it.
- 16 A. I discuss hormones in relationship to
- 17 ovarian cancer. Basically my opinion, or my
- 18 teaching to the medical students, is that ovarian
- 19 cancer has a very low, if any, association with
- 20 hormone exposure. So other than that, I can't
- 21 think of an environmental exposure to speak of.
- Q. And is that across all histologies?
- A. That is across all histologies, yes.
- Q. So if you have very little patient
- 25 interaction at MCW, is it fair to say that you

Page 18 1 never talk to patients about what caused their 2 cancer? A. I do not at MCW, no. 4 Q. Is it also true that determining the 5 cause of a women's cancer is just not part of your 6 normal care and treatment of the patient? 7 A. We're speaking strictly of ovarian? 8 Q. Yes. 9 A. No, because the laboratory performs 10 studies, genetic studies. So for example, if a 11 woman has a BRCA1 or BRCA2 mutation, I would opine 12 that that mutation was probably the cause of her 13 cancer. Sorry, let me just make sure I'm on mute. Q. Okay. And if you need to take a call at 15 any time, I --16 A. No, that's fine. 17 17 Q. I don't mind taking a break. 18 So aside from genetic screening and 19 studying germline mutations, do you ever consider 20 any other causes of ovarian cancer or do you ever 21 try to discern the cause of any of your patient's 22 ovarian cancers? 23 23 MR. HEGARTY: Objection to form. 24 THE WITNESS: No. Ovarian cancer, like 25 most solid tumors, the vast majority of them occur 25 cancer cell. So that is the most common cause of Page 19 1 sporadically. So that is the most common cause of 1 cancer. 2 their cancer. 2 3 BY MR. DEARING: Q. So let me just ask you. In your opinion, 5 are there any known causes of ovarian cancer? A. Yes. I think I discussed the genetic 7 mutations in the cancer genes. Also probably the 8 most common cause for ovarian cancer in most solid 9 tumors is mismatched repair gene -- mismatched 10 repair gene overwhelming -- or overwhelming 11 gene -- mismatch repair genes from normal cell 12 division. 12 Q. And the mismatch repair gene disruption 14 is because of some kind of DNA damage typically, 15 isn't it? A. So every time a cell divides, the 17 machinery of the cell has to copy the entire genome 18 of that cell, which basically has all of the DNA 19 that is within every one of our cells. Needless to

20 say, that is an immense amount of copying, and

So there are four base pairs:

23 adenine, guanine, cytosine, uracil in the case of

24 RNA, and those are basically put down in a row by a

25 molecule called the polymerase. And every once in

Page 20 1 a while, instead of putting an A, an adenine, it 2 puts down a G line. That is a -- that is a 3 mismatch. But there's another molecule that 5 follows called a mismatch repair molecule. And it 6 detects the fact that there's a G instead of an A, 7 and it knocks off the G and puts in an A. And all 8 of this is occurring at vertiginous speed. If there are too many mistakes, or 10 even if there aren't too many mistakes, but the 11 mismatch repair protein doesn't detect the error, 12 that base pair will remain in the daughter cell. 13 And that -- most of the time it doesn't matter, 14 because that base pair will either create a 15 nonviable cell, meaning it was in a gene that was 16 so critical that the cell dies, or it is silent. It doesn't matter because it occurred 18 in a piece of DNA that wasn't transcribed, but 19 occasionally it will result in a mutation that 20 gives the cell an advantage. And those are called 21 mutations that will progress towards 22 immortalization of the cell. And following immortalization, that 24 cell will continue to have mistakes and turn into a

Page 21

And this is all really outlined

3 beautifully in a publication by an Italian author

4 called Tomasetti in a landmark publication. And

5 I'm forgetting the title of that. But if you -- if

6 you put that into -- into PubMed, it'll pop out

7 pretty high on the list.

Q. As I understand it, isn't it true that

9 the BRCA1 and BRCA2 mutations directly impact this

10 mismatch repair gene? In other words, it disrupts

11 the repair mechanism?

A. The way BRCA1 and BRCA2 mutations work is

13 that they are antioncogenes. They slow down the

14 rate of replication. By slowing down the rate of

15 replication, you actually cause the mismatch repair

16 proteins to be able to handle the work. But if you

17 accelerate replication, the odds of getting a

18 mutation are much, much higher. So that's the way

19 most cancers are caused.

20 I'll give you an example in my field.

21 Cervical cancer. Human papilloma virus has a

22 protein that stops two antioncogenes. If you take

23 a normal cervical cell, the rate replication is

24 once every probably couple of weeks. If you

25 introduce HPV, the rate of replication is every six

22

21 there are mistakes made.

- 1 hours. So all of a sudden you have increased the
- 2 probabilities of getting a mutation many-fold.
- Q. Okay. Is it true that the main driving
- 4 cause of a repair disruption is some damage to the
- 5 DNA of a cell?
- 6 A. I'm not sure I can answer that. I'll 7 give you --
- 8 Q. Let me ask it a different way. I
- 9 understand that constant replication may have its
- 10 own inborn mismatch mistakes, I'll call them, and
- 11 they just happen. But they also occur sometimes
- 12 when they're -- when the DNA is damaged, which
- 13 affects its ability to properly replicate or
- 14 affects apoptosis, where it doesn't die on its own
- 15 because it was improperly replicated. Is that a
- 16 fair statement?
- 17 MR. HEGARTY: Objection to the form.
- THE WITNESS: Yes, there are what are
- 19 called mismatch repair gene mutations, which are
- 20 mutations to the DNA. And the mutations occur in
- 21 the genes that produce the proteins that repair
- 22 mismatch based pairs. If a person has a mismatch
- 23 repair gene mutation, they have a much higher risk
- 24 of acquiring cancers. And, for example, in
- 25 endometrial cancer and in colon cancer, mismatch

- Page 24
 1 reasonable process that could take place in humans?
 - 2 MR. HEGARTY: Objection to form.
 - THE WITNESS: So one of the things that I
 - 4 try to do as a -- as you mentioned, as an expert,
 - 5 is not speculate, because speculation means that
 - 6 I'm just guessing.
 - 7 BY MR. DEARING:
 - Q. Right.
 - 9 A. So there are some topics that I just
 - 10 can't say yes or no to, and this is one of them.
 - Q. Well, is there any reason to think that
 - 12 because it's been demonstrated in a cell culture,
 - 13 it would not operate that way in a human body?
 - 14 A. There are many reasons.
 - 15 Q. Okay.

16

- A. So in a cell culture you have a static
- 17 situation, where you put the source of reactive
- 18 oxygen species right on top of the cells and it
- 19 remains there. In an animal, there's blood flow,
- 20 there's oncotic pressures that -- that prevent
- 21 things from going into cells or out of cells.
- 22 There are so many factors that can't be replicated
- 23 from in a static cell culture environment that
- 24 would make that information a very valuable piece
- 25 of information.

Page 23

1 repair gene mutations are, A, common, and a common 1

- 2 cause of those cancers.
- 3 BY MR. DEARING:
- 4 Q. I've seen studies where reactive oxygen
- 5 species can damage DNA in a way that may affect
- 6 proper replication. Do you agree that that's a
- 7 possibility as well?
- 8 MR. HEGARTY: Objection to the form.
- 9 THE WITNESS: That has been demonstrated
- 10 in cell cultures. To the best of my knowledge, it
- 11 has not been replicated in animals or humans. It
- 12 is an interesting phenomenon because reactive
- 13 oxygen species can alter DNA. The question is how
- 14 do -- how do reactive oxygen species access the
- 15 DNA.
- 16 BY MR. DEARING:
- 17 Q. Okay. Do you have an opinion about
- 18 whether that is true biologically, that reactive
- 19 oxygen species can damage DNA which can cause
- 20 disruption in proper replication?
- A. In cell culture I do believe that's true.
- 22 I don't think it's been demonstrated in animals.
- Q. Right. But one of the advantages of
- 24 being an expert witness is you're allowed to offer
- 25 opinions about things. Do you think that that's a

Page 25 Reactive oxygen species alters DNA in

- 2 cell culture, but how can we design a study to show
- 3 that it does so in animals. And that's -- that's
- 4 where I don't think it's been done yet.
- 5 BY MR. DEARING:
- 6 Q. Right. It seems to me that that would be
- 7 impossible to do.
- 8 A. Oh, I mean in -- we do horrible things to
- 9 laboratory animals. I'm pretty sure that we could.
- 10 Q. I've also read -- and I've heard
- 11 testimony about -- situations where molecules
- 12 or -- I'm trying to think of the right
- 13 word -- materials, can attach themselves to a DNA
- 14 helix and cause damage. For example, I was
- 15 cross-examining -- or deposing Dr. Chodash
- 16 (phonetic). Do you know Dr. Chodash -- Dr. Chodash
- 17 at Penn? He's a cell biologist.
- 18 A. I don't know him.
- 19 Q. Well, we had a long conversation in a
- 20 deposition about tobacco and lung cancer. And he
- 21 was trying to explain to me the current thinking of
- 22 how tobacco smoke in the context of tobacco causes

25 actually attach to the DNA which cause considerable

- 23 lung cancer. And he said there are -- there are
- 24 carcinogenic molecules in tobacco smoke that

7 (Pages 22 - 25)

	•					
	Page 26		Page 28			
	damage, which starts oncogenesis.	1 that fallopian tube epithelium is exposed to				
2	First of all, do you agree with that	2 pharmacologic levels of estrogen. So a woman				
3	notion about tobacco, or is that beyond your field	3 have 325 micrograms per deciliter of estrogen.				
4	of study?	4 ovary will have 25,000 micrograms per decilit				
5	MR. HEGARTY: Objection to form.	5 because it's generating it there, and it leaches				
6	THE WITNESS: Yeah, it's way beyond my	6 out into the circulation of the woman.				
	field of study. I had a early on a colleague	7 That incredibly high level of				
	ϵ	8 estrogen estrogen is a mitogen, meaning it				
9	to carcinogenesis, and I sat in many of his	9 causes the epithelium to replicate starts				
10	laboratory meetings because I was cloning a gene	10 causing that little inclusion to the cells				
	for him. And he basically was studying tobacco	11 inside that inclusion to replicate. And as we				
12	glycoproteins as a toxin to cells.	12 discussed several times already in this				
13	So his point of view was that these	13 conversation, increases replication, increases to				
14	tobacco glycoproteins cause injury to the cell	14 chance of mismatched repairs, and the possibili				
15	itself. Injury to cells causes increased	15	that that cell will become immortalized and			
16	replication. Increased replication causes mismatch	16 cancerous. So that's the way cancer can start				
17	repair, which causes mutations, which causes	17 inside the ovary.				
18	cancer. That was his line. I am completely	Cancer in the fallopian tube even				
19	unaware and doesn't mean it's not true	19 though there's a lot of people who claim that a				
20	unaware of tobacco proteins or sticking to DNA.	20 of it starts in the fallopian tube is really, in				
21	BY MR. DEARING:	21 my opinion, mostly in patients who have inherit				
22	Q. Okay. With regard to ovarian cancer, do	22 mutations. So BRCA most of the cancers in l				
23	you believe that oncogenesis occurs when the cell	23 in women start in the fallopian tube, and that's				
24	is damaged somehow and then it causes this	24 because they already have one gene down, one				
25	irregular replication and eventually transforms	25	25 allele there's two alleles and to get both of			
	Page 27		Page 29			
	into a clinical?	1	them you only need one mutation.			
2		2	So that's that's the reason it			
3	Q. It's never as simple as my questions, but	3 starts in the fallopian tube because there's so				
1	I'm trying to	4 many cells in the fallopian tube.				
5	A. I will explain.	5	Q. So I need to unpack that a little bit.			
6		6 So it seems inconsistent with regard to the				
7	71	7 inclusion phenomenon when you said a few minute				
1	carcinogenesis is that ovarian cancer starts in	8 ago that most ovarian cancers are not influenced by				
	epithelium of the fallopian tube. Now, there are		hormones. So there seems to be a maybe I'm not			
1	two sources of fallopian tube epithelium. One of		understanding it right, but			
1	them obviously in the fallopian tube. The second	11	MR. HEGARTY: Object to form.			
	is inside of the ovary. Every time the ovary	12	THE WITNESS: By external hormones.			
	ovulates, it opens up. And the fallopian tube	13	BY MR. DEARING:			
1	usually sits right on top of the ovary because it	14	Q. By external hormones.			
15	has to catch the egg as it comes out.	15	A. Correct.			
1 4 -			0 01			

16 Q. Okay.

17 A. And may I qualify that?

18 Q. Yeah.

A. So when you -- when you administer

20 hormones to a woman, you're basically administering

21 the levels of in the circulation. In the ovary,

22 the levels are just astronomically high.

23 Q. Is it fair to say that serous carcinoma

24 of the ovary is not thought to be influenced by

25 hormones?

8 (Pages 26 - 29)

23 inclusions in the ovary.

And as the ovary -- as the egg is

17 expelled, there's a lot of hemorrhage. There's a

18 lot of fibrin to stop the bleeding. And fibrin is

20 little piece of fallopian tube epithelium, and that

22 incorporated inside of the ovary. Those are called

25 estrin receptors. And once inside of the ovary,

Fallopian tube epithelium is -- has

19 like glue. And occasionally it'll pinch off a

21 piece of fallopian tube epithelium will be

Page 30	Page 32			
1 A. Because 70 percent of all ovarian cancer	1 MR. HEGARTY: Turn the next page.			
2 is serous, the answer is yes, it's influenced by	2 MR. DEARING: Which report are you			
3 the hormones pharmacologic levels of hormones in	3 looking at?			
4 the ovary.	4 THE WITNESS: This is the Converse, but			
5 Q. And that would just apply to the	5 it's present in all of them.			
6 inclusion cancer, not so much those in the	6 BY MR. DEARING:			
7 fallopian tube?	7 Q. Okay.			
8 A. Well, if you look at the at the	8 A. It's the first few paragraphs.			
9 literature, most fallopian tube cancers begin in	9 Q. First few paragraphs of what section? Of			
10 the fimbriae. And the fimbriae is sitting right on	10 the whole thing?			
11 top of the ovary, which has all that amount of	11 A. It would be in the			
12 hormone. So it in my opinion, it does influence	MR. HEGARTY: Above the brief clinical			
13 those in the fallopian tube as well.	13 history part.			
14 Q. Since 75 or 80 percent of ovarian cancers	14 MR. DEARING: Okay.			
15 are serous?	15 THE WITNESS: So almost 25 percent of			
16 A. I said 70, but go ahead.	16 women diagnosed with ovarian cancer carry germline			
17 Q. Oh, I'm sorry. Okay, we'll use your	17 mutations in cancer susceptibility genes, including			
18 numbers. Assuming 70 percent of ovarian cancers	18 BRCA1 and BRCA2.			
19 are serous, do you have an opinion as to what	19 BY MR. DEARING:			
20 percentage of those actually start in the fallopian	20 Q. Okay.			
21 tube?	21 A. BRCA1 and BRCA2 account for approximately			
22 A. Yes, I have an opinion. If we're talking	22 15 percent of germline mutations, with the other			
23 about non-BRCA mutants, probably 90 percent of them	23 cancer-associating genes and then I give a list			
24 start in the ovary. Only ten percent at the most	24 of a long list accounting for the rest.			
25 start in the fallopian tube. If we're talking	25 Q. Right. So 15 percent of 25 percent is			
Page 31	Page 33			
1 about BRCA mutants, the proportion is almost	1 what percent to the overall population of women			
2 exactly reversed. About 80 percent will start in	2 with cancer?			
3 the fallopian tube and 20 percent in the ovary.	3 A. No, I think 15 percent of all women with			
4 Q. Is it fair to say that only about five	4 ovarian cancer carry germline mutations in BRCA1			
5 percent of ovarian cancers I'm sorry only	5 and BRCA2.			
6 five percent of women diagnosed with ovarian cance	d Q. Okay. This says 25 percent of women			
7 carry the BRCA1 and BRCA2 mutation?	7 diagnosed with ovarian cancer carry germline			
8 A. You know, I haven't I haven't thought	8 mutations. And then it says approximately			
9 about the numbers lately, but I think it's higher	9 15 percent of germline mutations I'm			
10 than five percent.	10 sorry BRCA1 and BRCA2 account for approximately			
11 Q. Well, I've read that only only	11 15 percent of germline mutations. So aren't you			
12 15 percent or so of all ovarian cancers are thought	12 talking about 15 percent of the 25 percent?			
13 to be derived from genetic predisposition or or	13 A. The way I worded it, that would be it.			
14 inherited mutations. Is that a fair number?	14 But I'm pretty sure it's 15 percent of all germline			
MR. HEGARTY: Objection to the form.	15 mutations.			
16 THE WITNESS: I'm going to check my	16 Q. Okay. That's where I got my five			
17 report, because I comment on that in my report.	17 percent. It's actually 3.5, 3.7 percent. Okay.			
18 BY MR. DEARING:	18 So I understand that all ovarian			
19 Q. Okay. I didn't remember that. Is there	19 cancers are caused by some kind of genetic defect,			
20	20 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			

20 whether it's a mismatch, replication, or something.

21 And as I understand your testimony, in your

22 opinion, the only known cause of that mismatch

MR. HEGARTY: Objection to the form.

23 carcinogenesis is an inherited mutation; right?

24

25 BY MR. DEARING:

21

22

23

25

20 one -- is there a report you're going to first?

MR. HEGARTY: I can show him where I

MR. DEARING: Sure. Of course.

A. It's in all of them, so...

Q. Okay. All right.

24 think he wants to look at.

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1 Q. Other than the fact that it can happen on

- $2\,$ its own sporadically, the only known cause of the
- 3 damage is an inherited gene mutation?
- 4 MR. HEGARTY: Object to the form.
- 5 THE WITNESS: The only association strong
- 6 enough to -- to claim that it's causal is a -- a
- 7 mutation in one of those genes, yes.
- 8 BY MR. DEARING:
- 9 Q. And when you're discerning the cause in
- 10 an association that's strong enough, what would be
- 11 a relative risk range where you think, okay, now
- 12 that's a causal association?
- 13 MR. HEGARTY: Objection to the form.
- 14 THE WITNESS: I -- I've tried to make
- 15 that assessment. I don't think there is a line
- 16 anywhere. I think that associations that are above
- 17 two or three are very strong associations that are
- 18 worth investigating. But again, there is no line.
- 19 There are very, very strong associations that turn
- 20 out to be nothing.
- 21 BY MR. DEARING:
- 22 Q. Right.
- 23 A. Like --
- Q. You talked about that in your report.
- 25 A. Correct. And then there are associations

- 1 Q. Even at two percent is indeterminate?
 - 2 MR. HEGARTY: Objection to form.
 - THE WITNESS: Yeah. It's a weak
 - 4 association. Indeterminate meaning I wouldn't --
 - 5 if I was in Vegas, I wouldn't bet on it.
 - 6 BY MR. DEARING:
 - 7 Q. So is there a degree of certainty that
 - 8 you would require before you would acknowledge or
 - 9 agree that something is likely to be a cause of a
 - 10 particular cancer?
 - 11 A. So it is my opinion that associations are
 - 12 extremely important to know about so that you can
 - 13 investigate it. In and by itself, an association
 - 14 is not causal. Obviously if you ever got an
 - 15 association where a hundred percent of people got
 - 16 something, whereas if they didn't have it,
 - 17 zero percent would get it, then I would say yeah,
 - 18 that's causal. But other than that, you have to
- 19 prove it. And to prove it, you have to show a
- 20 mechanism. And that's the way science should work.
- 21 Q. Right. I guess what we're talking about
- 22 here is assessment of risk. And so if you're
- 23 looking at a relative risk, let's say in the 1.5 to
- 24 two range, would you think that risk warrants
- 25 further investigation?

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1

- 1 like the association with BRCA. You were talking
- 2 its either five or 15 percent. It's really low,
- 3 right? It's very, very low. But somebody chased
- 4 it, and it was true. So it can be -- you know, a
- 5 15 percent is -- is a relative risk of 1.15.
- 6 So -- so -- and that's the problem
- 7 with biology. It's not physics where you can have 8 a number. It's -- it's biology.
- O And Lamma sists that
- 9 Q. And I appreciate that. That's why I
- 10 asked you sort of a range.
- 11 A. Yeah.
- 12 Q. But you think a two- to three-fold
- 13 increased risk is a strong association?
- 14 A. I believe that it -- certainly a three
- 15 increase in relative risk is a strong association.
- 16 Q. How would you characterize a doubling of
- 17 a risk, a twofold increased risk?
- 18 A. A doubling of the risk?
- 19 Q. Right. So you're talking about three,
- 20 but I'm going down to two. How would you
- 21 characterize two as far as a strength of
- 22 association?
- A. And again, I'm not a statistician, so
- 24 this is an opinion. I would say it's
- 25 indeterminate.

MR. HEGARTY: Objection to form.

- THE WITNESS: Yes. I think any risk
- 3 is -- is -- warrants further investigation.
- 4 BY MR. DEARING:
- 5 Q. And if that risk proved to be, after
- 6 further investigation, truly between a 1.5 and two
- 7 relative risk, if that risk was associated with a
- 8 commercial product, do you think that that would
- 9 warrant a warning to the user of that product?
- 10 MR. HEGARTY: Objection to the form.
- 11 Calls for speculation.
- 12 THE WITNESS: So when you say further
- 13 investigation shows that there's still a 1.5 risk,
- 14 that doesn't make sense. Because further
- 15 investigation needs to show a cause, either a
- 16 biologic or a physical cause. Exposure to
- 17 radiation gives you certain types of cancers.
- 18 There's an association with that. Then you go to
- 19 the laboratory or to the clinic -- no,
- 20 laboratory -- and you say why would it cause
- 21 cancer. And then you see that radiation causes
- 22 direct damage to DNA. Now you have the
- 23 association, hey, people exposed to radiation get
- 24 cancer. Go into the laboratory and you say hey,
- 25 when you look at the cells that are exposed to

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1 radiation, they have DNA damage. Now you've linked 1 prospective studies that are not blinded or -- but

- 2 the risk to a cause. And that's what you need to
- 3 say that something is causal.
- 4 BY MR. DEARING:
- Q. Well, isn't it true that scientists went
- 6 years, maybe decades, looking at tobacco and lung
- 7 cancer before they realized how it was causing lung
- 8 cancer, but the association was clear decades
- 9 before the how was ever proven; right?
- 10 MR. HEGARTY: Objection to the form.
- 11 THE WITNESS: I don't think -- and I
- 12 don't know enough history on tobacco to say that
- 13 you're right or wrong, but the toxins in tobacco
- 14 smoke were shown very early in the process, and
- 15 whether they were hiding it or whether they were
- 16 not motivated to pursue it -- after all, four out
- 17 of every five doctors smoked Clarks.
- 18 BY MR. DEARING:
- Q. Have you ever published or lectured on
- 20 any topics associated with talcum powder?
- 21 A. I have not.
- 22 Q. You mentioned briefly some epidemiology
- 23 studies in your report. But in my opinion, there's
- 24 not a lot of depth to the explanation. Are you
- 25 intending to offer epidemiology opinions at trial?

- Page 40
- 2 they are randomized. And then after that is
- 3 prospective studies that are not randomized. And
- 4 then after that is retrospective studies, and then
- 5 after that is opinion, or something along those
- 7 Q. Where would you rate meta-analyses and
- 8 systematic reviews?
- A. Because I'm not an epidemiologist, I
- 10 don't have the knowledge base to place it. Because
- 11 meta-analyses are actually a relatively new thing.
- 12 And some people think that they are very high in
- 13 the level of evidence, and some people basically
- 14 think well, garbage in, garbage out, right?
- 15 If you have 100 really bad studies and
- 16 you put them all together, does that give you a
- 17 really good study? So my opinion is guarded
- 18 regarding meta-analyses. Obviously, there
- 19 are -- there are some meta-analyses that have
- 20 proven true by doing a randomized double blind
- 21 study and the same result occurs.
- 22 And a very good friend of mine,
- 23 Malcolm Pike, gave an entire lecture regarding a
- 24 bunch of retrospective meta-analyses that predicted
- 25 the outcome of a prospective randomized study. But
- 1 MR. HEGARTY: Objection to the form.
- 2 THE WITNESS: I'm -- I'm only going to
- 3 opine that prospective studies carry more
- 4 credibility than retrospective studies, and
- 5 that -- and that the prospective studies that have
- 6 been done regarding talcum ovarian cancer failed to
- 7 show an association.
- 8 BY MR. DEARING:
- Q. Okay. Have you taken courses in
- 10 epidemiology?
- A. I took one in medical school.
- 12 O. Right.
- 13 A. That's about it.
- Q. Okay. What is the source of your opinion 14
- 15 that prospective studies are more reliable than
- 16 retrospective studies?
- 17 A. So it's not me saying that. When you
- 18 look at levels of -- it was in the front of my
- 19 mind, and -- levels of evidence. There's five
- 20 levels of evidence. I believe the most robust is a
- 21 double blind prospective randomized study. That's
- 22 the panacea, right? Nobody knows anything until
- 23 the very end, and then you find out whether
- 24 something had to do with an effect.
- 25 After that, the fourth level is

- 1 others don't. So it just depends. And I -- I
- 2 think that generalizing meta-analyses as better or
- 3 worse is not a very good practice.
- Q. The last question asked what was the
- 5 source of your opinions about this. You said these
- 6 aren't my opinions, and you told us about the
- 7 levels. But where are you getting this information
- 8 from?
- 9 A. These are published. And I -- I can't
- 10 quote you the article, but these are well-respected
- 11 epidemiologists who got together and formulated
- 12 these five levels of evidence. And -- and most
- 13 people follow them.
- 14 And if you look at guidelines, for
- 15 example -- so I worked at one point with the
- 16 American Society of Colposcopy and Cervical
- 17 Pathology, and I was on the high-grade dysplasia
- 18 committee, and we published guidelines. If a woman
- 19 has a PAP smear that's like this, what should you
- 20 do. And then we would say you should biopsy 21 through colposcopy, and then we would state level
- 22 of evidence. Level of evidence is -- level for
- 23 evidence or whatever. Because there are
- 24 prospective trials showing that cytology predicts
- 25 pre-cancer.

Page 42 Page 44 1 So those are -- most of the guidelines 1 epidemiologists to do that? 2 will have levels of evidence. So if you go to any A. Hopefully. 3 of the large societies that publish guidelines, 3 Q. It won't be me. 4 they will use those five categories. 4 I see you brought materials with you Q. Well, would you agree that epidemiology, 5 today. You have several binders. Were those 6 like most areas of science, is an evolving science? 6 provided to you by the lawyers? 7 In other words, what people thought 30 years ago 7 A. Yes, they were provided to me by the 8 may not be how they think about something now? 8 attorneys for the defense. The materials that MR. HEGARTY: Objection to the form. 9 refer to my opinions were authored by me. The 10 THE WITNESS: I -- I agree with your 10 materials that I referred to were authored by your 11 comment. All science evolves as knowledge becomes 11 experts also. 12 available. And if it doesn't, then you're just 12 Q. Okay. 13 being dumb about it. 13 A. But they're in there. 14 14 BY MR. DEARING: Q. Oh, the plaintiff expert reports are in Q. I saw in your CV that you actually 15 the binders? 16 participated in a case control study. And before I 16 A. Yeah. Yes. 17 ask you -- on ovarian cancer. And before I ask you 17 Q. I mentioned this before, but we were sent 18 about that, would you agree with me that case 18 some very large data files two days ago that I 19 control studies, despite where they may fall on 19 assume are mostly photomicrographs. But because of 20 this hierarchal of evidence, can provide very 20 the volume of the data, we were unable to download 21 useful, helpful information with regard to 21 them and get them opened in any useable way. Did 22 associations? 22 you bring photomicrographs with you in addition to 23 23 the ones that are already incorporated into your A. There's no --24 MR. HEGARTY: Objection to the form. 24 reports? 25 THE WITNESS: There's no question that 25 A. I did not. Page 45 1 that's true. They provide very useful information. Q. Okay. 1 2 And in fact, case control studies are probably the A. The -- the files that you're referring to 3 beginning of most fact-finding journeys in 3 are accessible. And I can almost certainly 4 medicine. 4 download one, maybe. This is an air book computer, 5 BY MR. DEARING: 5 and they're fairly limited storage space. The Q. Is it true also that case control studies 6 files are usually one-and-a-half gigabytes in size. 7 can often formulate or postulate an association 7 But the -- basically those files -- each file 8 faster than a cohort study because you don't have 8 represent one glass slide of the surgical pathology 9 to wait for the end disease to occur years down the 9 case of that patient. 10 road? 10 So in the case of Ms. Balderrama, 11 MR. HEGARTY: Objection to the form. 11 which I actually -- I don't have yet, it would be 12 THE WITNESS: That is correct. That's 12 about a hundred of them, a hundred slides. 13 one of the advantage of case cohort studies. 13 Q. Okay. What do you mean you don't have 14 BY MR. DEARING: 14 yet? 15 15 Q. Back to what started this whole thing. A. They're currently being -- I'm maybe not 16 Other than just a statement about the hierarchal 16 remembering right, but I have one case that's 17 reliability of case control versus cohort studies, 17 currently being digitized. 18 do you intend to discuss any of the specific 18 Q. Okay. 19 detailed epidemiology studies that you mention in 19 A. And it's not in my computer file yet. If 20 your report at trial? 20 it becomes important for you to see those, we can 21 MR. HEGARTY: Objection to form. 21 walk to my office, which is about a five-minute 22 THE WITNESS: I do not intend to do so, 22 walk, and I can show you all of them in my desktop.

MR. DEARING: Well, more importantly than

24 me being able to see them is us being able to

25 attach relevant photomicrographs as exhibits to

23

24 BY MR. DEARING:

Q. 'Cause both sides will be calling

23 no.

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- 1 this deposition. But what I could do is I'd like
- 2 to just reserve the ability to examine the doctor
- 3 at some future date when we actually have the
- 4 photomicrographs, if it's necessary, to point out
- 5 relevant features that he thinks bear on our
- 6 clients' conditions.
- 7 MR. HEGARTY: We're agreeable to cross
- 8 that bridge if we ever come to it --
- MR. DEARING: Okay.
- 10 MR. HEGARTY: -- through discussions
- 11 between the parties.
- 12 MR. DEARING: Okay. I'm confident we can
- 13 work it out, so...
- 14 BY MR. DEARING:
- 15 Q. Do you know how Johnson & Johnson ever
- 16 learned your name as far as before they approached
- 17 you about investigating this talc ovarian cancer
- 18 issue?
- 19 MR. HEGARTY: Objection to form. Also, I
- 20 know you're not meaning intentionally -- or
- 21 misrepresenting. Johnson & Johnson did not
- 22 approach --
- 23 MR. DEARING: Let me re-ask the question.
- 24 Thank you.
- 25 BY MR. DEARING:

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- Q. Do you know how the lawyers for Johnson &
- 2 Johnson got your name to approach you about
- 3 possibly being an expert witness in this
- 4 litigation?
- MR. HEGARTY: I'll object and instruct
- 6 you not to respond to the extent that would require
- 7 you to disclose information that the attorneys
- 8 provided to you as part of the -- of our
- 9 communications. But if you can answer apart from
- 10 anything you were told or you learned about from
- 11 discussions with counsel, then you can answer.
- 12 THE WITNESS: I am not completely certain
- 13 about how they learned from me, other than at the
- 14 time I was working very closely with Bob Kerman,
- 15 and I know Bob has been an expert for the defense.
- 16 And my -- my best guess is that Bob gave them my
- 17 name as a possible expert.
- 18 BY MR. DEARING:
- 19 Q. Okay. Have you ever been a paid speaker
- 20 for Johnson & Johnson or any Johnson & Johnson
- 21 company?
- 22 A. I have not.
- Q. Have you ever received any contributions
- 24 or funding or research grants from Johnson &
- 25 Johnson or any of their companies?

- 1 A. I have not.
- 2 Q. As you sit here today, can you tell me as
- 3 best that you can recall what other corporations
- 4 you have testified on behalf of?
 - MR. HEGARTY: And that would be limited,
- 6 as Mr. Dearing's question said, to those where
- 7 you've actually testified versus those that you
- 8 might have consulted with but were never disclosed
- 9 as an expert and never testified for.
- 10 THE WITNESS: So I -- other than Johnson
- 11 & Johnson, Phillip Morris, and maybe another of the
- 12 tobacco companies.
- 13 BY MR. DEARING:
- 14 Q. That's all? I used to have a longer
- 15 list, but I didn't bring it.
- A. Yeah, I think as far as product liability
- 17 that's it. I mean, Johnson & Johnson and
- 18 Phillip and the tobacco companies.
- 19 Q. And you were first retained by the
- 20 lawyers for Johnson & Johnson about ten years ago.
- 21 Does that sound right?
- 22 A. Yeah, I think the first case was 2012.
- 23 So a little bit more than ten years ago.
 - Q. Well, if the first case was in 2012, were
- 25 you retained before 2012?

- A. Probably, but I -- no exact memory of it.
- 2 The only way I figured out 2012 is we went back in
- 3 the records and saw that it was 2012.
- Q. It feels like a lifetime to me --
- A. Yeah.
- Q. -- it's been going on.
- 7 A. I mean, I was young back then.
- Q. Same. In those twelve years or so has
- 9 Johnson & Johnson's lawyers ever provided you with
- 10 any internal company documents to review?
- A. They have not. The way that I have seen 11
- 12 internal company documents is when -- when you show
- 13 them to me. Or not you, but --
- 14 Q. On cross-examination?
- 15 A. -- the attorney -- the attorneys show
- 16 them to me, yes.
- 17 Q. So the only corporate documents you've
- 18 ever seen from Johnson -- strike that.
- 19 So the only Johnson & Johnson
- 20 corporate documents you've ever seen are those that
- 21 were shown to you as part of cross-examination in a
- 22 trial?
- 23 A. That is correct, or deposition.
- 24 Q. There are reference lists attached to all
- 25 of your reports. Did you prepare that reference --

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1 those reference lists?

- A. Yes.
- 3 Q. And do you rely on all of those
- 4 references in forming your opinions?
- A. I used those references to form my
- 6 opinions. I'm not -- I guess using them to form my
- 7 opinion and relying on them could be synonyms. But
- 8 I think the legal term "rely" brings some luggage
- 9 with it.
- 10 Q. Okay. Not trying to sneak luggage in on 11 you.
- 12 A. Okay.
- 13 Q. Have you read everything that's on your
- 14 reference list?
- A. Yes. At one point or another I've read
- 16 every single one of those articles, which made me a
- 17 lot of money.
- Q. Right. One more question about the
- 19 epidemiology. You list several epidemiology
- 20 studies and articles in your reference list. But
- 21 would you agree with me that epidemiology studies
- 22 don't really inform your pathology opinions in
- 23 these cases?
- 24 A. You're --
- 25 MR. HEGARTY: Objection to the form.

1 body. And I saw it a couple of times in -- in

- 2 ovaries very early on in my training. Back then
- 3 there was still women who had been -- undergone 4 surgery, and surgeons had powdered gloves. So I
- 5 saw the sequela of talc in the female pelvis in
- 6 probably a handful of cases.
- So I know what it -- what it does. So
- 8 it never crossed my mind that it would be a cause
- 9 of ovarian cancer. And then I -- I started reading
- 10 more and more about it and -- and -- and formed
- 11 opinions about it.
- 12 Q. Is it your opinion or even common
- 13 knowledge that talc exposure in the pelvis
- 14 will -- will initiate or cause an inflammatory
- 15 reaction?
- 16 MR. HEGARTY: Objection to the form.
- 17 THE WITNESS: A very specific
- 18 inflammatory reaction, absolutely.
- 19 BY MR. DEARING:
- 20 Q. And what specific reaction are you
- 21 referring to?
- 22 A. It will form a foreign body reaction.
- 23 Q. And those foreign body reactions would
- 24 include macrophage activity, granulomas --
- 25 granulomatis activity, and even multi-nucleated

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THE WITNESS: So they inform it a little

2 bit.

1

- 3 BY MR. DEARING:
- Q. Okay.
- A. In other words, epidemiologic studies say
- 6 there's an association between talc and ovarian
- 7 cancer. So I go to the microscope and I say well,
- 8 is there any evidence that there's talc present in
- 9 the ovary while the ovary was vital, meaning in the
- 10 person's body. So in that way it does influence
- 11 me, because -- I look at ovaries very, very
- 12 differently since we began this litigation process.
- Q. Okay. I believe you've testified years
- 14 ago, maybe more recently, that you actually learned
- 15 about the effects of talc in the human body in
- 16 medical school; is that right?
- 17 MR. HEGARTY: Objection to the form.
- 18 THE WITNESS: It is likely so, yes.
- 19 BY MR. DEARING:
- Q. Did you have any opinions about talcum
- 21 powder and ovarian cancer before the lawyers for
- 22 Johnson & Johnson approached you about serving as
- 23 an expert in this litigation?
- A. To tell you the truth, it never crossed
- 25 my mind, because I know what talc does inside the

- 1 giant cell activity?
- 2 MR. HEGARTY: Object to the form.
- 3 THE WITNESS: So it will cause what
- 4 in -- in pathology and medicine is called a
- 5 granulomatous reaction. Granulomatous --
- 6 granulomas are formed by three types of cells, two
- 7 of which are very closely related. One of them is
- 8 a macrophage. The other one is the foreign body
- 9 giant cell. I'm sorry. One of them is the
- 10 microphage. The other one is the multinucleated
- 11 giant cell. And the third is the lymphocyte, okay?
- 12 Now, there are two types of
- 13 granulomas. There are immune granulomas, which are
- 14 generated by -- most of them -- infectious organism
- 15 such as tuberculosis or fungi, and then there's the
- 16 foreign body granulomas which are formed by foreign
- 17 bodies.
- 18 BY MR. DEARING:
- Q. Is it true to say that granulomas are
- 20 essentially a conglomeration of macrophages all
- 21 coming together?
- 22 MR. HEGARTY: Objection to the form.
- 23 THE WITNESS: It is -- it is a -- your
- 24 description very much describes what a granuloma
- 25 is.

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1 BY MR. DEARING:

- Q. When you were observing those effects of
- 3 talc in the female pelvis, did you ever actually
- 4 look at the talc particles that were left behind?
- 5 A. Yes.
- 6 Q. And would you agree with me that those
- 7 talc particles -- the size of those talc particles
- 8 would dictate the type of response? In other
- 9 words, if the particle left behind was five microns
- 10 in diameter, that would most likely attract a
- 11 macrophage. If it was a hundred microns in
- 12 diameter, that might attract something larger.
- 13 Would you agree?
- MR. HEGARTY: Objection to the form.
- 15 THE WITNESS: As a general rule, that is
- 16 correct. But I have seen foreign body granuloma
- 17 with foreign body giant cells in particles as small
- 18 as three microns. And I have photographs of that.
- 19 So -- so as a general rule, the smaller particles
- 20 are phagocytized by macrophages. The larger
- 21 particles cannot be phagocytized because they're
- 22 too large for the macrophage to engulf the
- 23 particle, so then that causes a granuloma.
- 24 BY MR. DEARING:
- Q. Okay. Is it also true that sometimes

- 1 not for very long.
 - 2 BY MR. DEARING:
 - Q. Do you agree that once tissue's removed
 - 4 from the body, all inflammatory processes, all
 - 5 macrophages, everything just stops?
 - 6 A. You are --
 - 7 Q. In other words, the cells die and nothing
 - 8 else happens?
 - 9 A. You are correct. Within probably seconds
 - 10 of the organ being devitalized, those processes
 - 11 will stop.

14

- 12 Q. Is it also true that macrophages may be
- 13 attracted to dead cancer cells?
 - A. Absolutely.
- 15 Q. And it's not uncommon to actually see a
- 16 macrophage sequester a dead cancer cell; right?
- 17 A. The macrophages engulf the rest of the
- 18 cells. Once the cell dies, most of the time it
- 19 fragments and then the macrophage will eat the
- 20 fragments of the -- of the dead cell.
- Q. When you are looking at surgical slides
- 22 from an ovarian cancer patient under routine
- 23 microscopy, do you typically observe macrophages,
- 24 or is that something you're just not looking for?
- A. Oh, no, we look for it very carefully for

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1 macrophages die during the phagocytosis process for

- 2 whatever reason, either they can't adequately
- 3 sequester and phagocytize the particle or the
- 4 particles's just too big?
- 5 MR. HEGARTY: Objection to form.
- 6 THE WITNESS: You are correct,
- 7 there -- there is a phag -- a macrophage can die in
- 8 the process of phagocytosis.
- 9 BY MR. DEARING:
- 10 Q. And when that occurs, more macrophages
- 11 typically come to take its place; is that right?
- 12 A. Yes. A naked particle cannot exist
- 13 without a foreign body reaction to it.
- 14 Q. But wouldn't you agree that there may be
- 15 a transition period where a macrophage dies,
- 16 another macrophage has not taken it up yet, and the
- 17 particle is just sitting there by itself?
- MR. HEGARTY: Objection to the form.
- 19 THE WITNESS: Yeah, I -- I -- I'm not
- 20 sure anybody can answer that question because
- 21 usually it's not just one macrophage that shows up.
- 22 When there's a foreign body, probably thousands of
- 23 macrophages are -- are around. Will there be a
- 24 point of a macrophage dies where that particle is
- 25 exposed to tissue itself? Likely. Likely. But

- 1 a variety of reasons. Many cases of ovarian
- 2 cancer today, as opposed to 30 years ago, have
- 3 what -- have undergone what's called neoadjuvant
- 4 chemotherapy, where the woman receives chemo before
- 5 the surgery. And actually one of the parameters
- 6 that is non-optional in our synoptic forms is the
- 7 effect of chemotherapy on the tumor. And we
- 8 measure that predominantly by the presence of
- 9 macrophages.
- 10 So there -- in the case a woman will
- 11 have received chemotherapy and we'll see massive
- 12 amounts of macrophages and only a little bit of
- 13 tumor then we -- we categorize that as an excellent
- 14 response. If there are some macrophages but a lot
- 15 of tumor left, we'll say moderate response. And if
- 16 we can't see any evidence of macrophages, we'll say
- 17 minimal response.
- 18 I'll -- I'll categorize it by saying
- 19 that it's -- that it's not a perfect attempt to
- 20 categorize the effect of chemotherapy on the tumor
- 21 because there are cases where radiologically the
- 22 woman had large ascites, an enormous amount of
- 23 carcino -- carcinomatosis in the omentum and
- 24 peritoneum, and at the time of surgery, there's
- 25 very little tumor. And we'll look at it under the

Page 58 Page 60 1 microscope and there won't be a single macrophage. 1 BY MR. DEARING: 2 And I can't explain that, but it happens. So --Q. Is it also true that most pathologists, 3 and, again, biology, it's not physics. 3 surgical pathologists, will not polarize the slides Q. In cases where women have not had 4 when they're looking at the surgical slides? 5 neoadjuvant chemotherapy are you also looking for 5 MR. HEGARTY: Objection to form. 6 macrophages in typical cervical slides? 6 THE WITNESS: Not unless there's a reason A. Yes. So tumors will have a cell turnover 7 to. And the reason would be granuloma. 8 for a variety of reasons. Some people use the term 8 MR. DEARING: Okay. We've been going 9 they outgrow their blood supply and large areas of 9 about an hour and a half. Does anybody need a 10 that tumor become necrotic. So we -- we will 10 break? 11 11 frequently find macrophages. MR. HEGARTY: Yeah, I could use a short 12 The other thing that -- that a lot of 12 break. 13 people don't know is that just because a woman has 13 MR. DEARING: Okay. 14 14 cancer doesn't mean she may not have other (Break taken.) 15 diseases. And in -- in my practice I have 15 BY MR. DEARING: 16 discovered at least five women who have had -- who 16 Q. We were talking about the inflammatory 17 had tuberculosis in addition to their ovarian 17 reactions on the pelvis left by -- or caused by the 18 cancer. And I found that out because there were 18 talc left behind from abdominal surgeries. And my 19 question is, you said you observed granulomas and 19 granulomas, and I stained them, and there were 20 microbacteria in them, so... 20 granulomatous reactions. Do you have any opinion 21 21 about whether a chronic inflammation like that in And that can be really important 22 because -- particularly if she hasn't received 22 the pelvis can cause metaplasia or -- can initiate 23 neoadjuvant chemotherapy and she has tuberculosis, 23 a cancer process? 24 and then you give her chemotherapy and you make her24 MR. HEGARTY: Objection to the form. 25 immune deficient, she can die of the tuberculosis. THE WITNESS: I do have an opinion. Page 59 Page 61 1 So -- so it's really important for us to look at. 1 BY MR. DEARING: Q. I appreciate that. And that sort of Q. What is that opinion? 3 seems like cutting-edge pathology. But based on A. Granulomatous inflammation has not been 4 your experience as a pathologist -- and you've 4 associated with carcinoma. 5 worked other places. I know you were at USC for a O. What negative health effects can a 6 long time -- isn't it true that most surgical 6 chronic inflammatory reaction cause in the pelvis? MR. HEGARTY: Objection to form. 7 7 pathologists, when they're looking, spending a few 8 minutes to diagnose a patient, that they're not 8 BY MR. DEARING: 9 looking for macrophages in those slides? Q. If any? 10 MR. HEGARTY: Objection to form. 10 A. Yes. It can cause and it does cause THE WITNESS: So it depends on the level 11 adhesions, meaning one organ sticks to another. 12 of macrophages, okay? Most even community 12 Adhesions are a source of pelvic pain in women. It 13 pathologists, if they find increased numbers of 13 is also a cause of infertility. So pain and 14 macrophages, they will not only detect it, but 14 infertility are the two sequela of talc-induced 15 likely try to find an explanation for it. And 15 chronic inflammation. 16 there are things called xanthomonas reactions that Q. Do you know about how many hours you've 17 are associated with genetic conditions that -- that 17 spent researching before you conclude that talc can 18 are important to detect, so... 18 cause cancer? You know what, let me ask a

16 (Pages 58 - 61)

20

23

25

22 body?

19 pre-cursor question to that. I'm sorry.

Is it your opinion that talc exposure

A. That is my opinion in the -- in the parts

Q. Okay. And do you know how much time you

21 cannot cause any kind of cancer anywhere in the

24 of the body that I'm aware talc has been used.

25 on it.

And again, another example, there

20 are macrophages in virtually every tissue that we

22 a macrophage in a tissue section. If it's the

23 level -- if it's at the level of what is normally

24 found in tissue, most pathologists will not focus

21 examine as pathologists. And it's normal to expect

	Page 62	Page 64				
1	spent researching to come to that conclusion?	1 talc-related opinions with any of your colleagues				
2		2 here?				
3		3 A. No, not with any I may have mentione				
	being retained by the lawyers for Johnson &	4 it in casual conversation, but not as a topic of				
	Johnson?	5 interest sorry, not as a topic of medical				
6		6 discussion. I may have said, yeah, I'm I'm				
7		7 going to be I'm examining this case that relates				
	lawyers for Johnson & Johnson, is it fair to say	8 to talc and ovarian cancer.				
	that's when you first started investigating whether	9 Q. Okay. But not substantively about your				
	talc can cause cancer in the parts of the body that	10 opinions?				
	you're familiar with?	11 A. Correct.				
12		12 Q. Have you ever showed anyone here your				
13	3	13 expert report?				
	yes.	14 A. Anyone at MCW?				
	BY MR. DEARING:	14 A. Anyone at MC w? 15 Q. Yes.				
16		16 A. No.				
	research you conducted before you reached a final	17 Q. What about when you were at USC, did you				
	conclusion that tale can't cause cancer?	18 ever show any of your colleagues there your expert				
19		19 reports?				
	it it I've read all of those articles to make	20 A. No.				
	sure that I was not opining without basis. So	21 Q. Has the topic of genital talc use in				
	probably, you know, a hundred hours.	22 ovarian cancer ever come up in your rounds or tumor				
23	-	23 boards or group meetings?				
	about the idea when Johnson & Johnson lawyers first					
23	approached you, the idea being whether talc can					
	Page 63					
1		1 related to the causes or risk factors of ovarian				
2	· ·	2 cancer?				
3	,	3 A. Yes.				
	never occurred to me.	4 Q. Do you remember what that publication				
5		5 was? Was it more than one?				
6		6 A. Yes. So I worked with a colleague whose				
	College of Wisconsin aware of the fact that you're	7 name was Louis DuBeau, B-E-A-U. And we looked at				
	offering opinion testimony in this ongoing	8 several genes regarding ovarian cancer and their				
	litigation?	9 role in ovarian carcinogenesis.				
10	•	10 Q. Do you know when that publication was?				
	consulting.	11 A. It was in I don't remember. I can				
12		12 Q. Is it on your is it on your CV?				
	opinions by anyone at the Medical College of	13 A. It's on my CV, yes.				
	Wisconsin before you go under oath offering them	14 Q. Okay. Might be easier for you to find it				
	somewhere?	15 than me. If you can just direct me to it.				
16		16 A. Sure. So reference number 21, the				
17		17 potential role of inactivated X chromosome in				
	advise the administration that you're doing legal	18 ovarian epithelial tumor development.				
	work for a company?	19 Q. Okay. I don't see Dr. DuBeau's name.				
20		20 A. He's				
	interest disclosure that I fill out in which I put	21 Q. Oh, yes, I do. Yes, I do.				
	all of the not all of them, but the law firms	22 A. He was the senior author.				
	that I work with and the issues that they that	23 Q. Is that the only publication?				
1 24	are involved.	A. No, the one beneath it as well. And then				
44	are involved.					

25 24, alterations in DNA methylation are early but

Q. Okay. Have you discussed your

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- 1 not initial events in ovarian tumorigenesis. Then
- 2 27, this is with Michael Press, WAF1/CIP1, gene
- 3 polymorphisms, an expression in carcinomas of the
- 4 breasts, ovary, and endometrium.
- 5 So I became involved in all of these
- 6 publications because of my expertise in
- 7 diagnostics. So as you probably heard, properly
- 8 classifying tumors is pretty important when you're
- 9 trying to determine if something causes it or not.
- 10 Q. Right. Was that your role for the most
- 11 part in these publications is diagnosing or
- 12 classifying the tumors?
- 13 A. Well, at the time I also had a molecular
- 14 biology laboratory, so I may have done some of the
- 15 tests in the lab. 34 is another example.
- MR. HEGARTY: Do you want him to keep
- 17 going, David?
- 18 BY MR. DEARING:
- 19 Q. I mean, I don't want to spend a lot of
- 20 time on it, but if any jump out at you, I'd like to
- 21 know about it, particularly with regard to risk
- 22 factors in ovarian cancer.
- A. 35, imbalanced expression of inhibin and
- 24 activin subunits in primary epithelial ovarian
- 25 cancer.

- Page 67
- 1 Q. Let me ask you this. What about in the
- 2 past ten years, have you published anything on
- 3 ovarian cancer?
- 4 A. Not to my knowledge, no.
- 5 Q. Do you have any opinions as to what may
- 6 cause primary peritoneal cancer, or would it be the
- 7 same causes we've already discussed for ovarian
- 8 cancer?
- 9 A. It would be the same causes, in my
- 10 opinion.
- 11 Q. Is it your opinion that most primary
- 12 peritoneal cancers also derive from the fallopian
- 13 tube?
- 14 A. From fallopian tube epithelium, yes.
- 15 Well, there's -- there's -- the serous ones will be
- 16 from fallopian tube epithelium. The endometrial
- 17 ones will be from endometriosis.
- 18 Q. You've opined that talc cannot cause any
- 19 type of ovarian cancer. Is that opinion based on
- 20 your opinion that talc can't reach the ovaries, or
- 21 that talc doesn't affect the tissue in a way that
- 22 might cause cancer when it gets to the ovaries?
- MR. HEGARTY: Objection to form.
- 24 THE WITNESS: Both.
- 25 BY MR. DEARING:

- 00
 - 1 Q. Both. Okay. So have you read studies
 - 2 supporting the idea that chronic inflammation can
 - 3 ultimately lead to cancer?
 - 4 A. Yes, I have read many studies that
 - 5 indicate that.
 - 6 Q. And do you agree that chronic
 - 7 inflammation does cause some types of cancer?
 - 8 A. Yes.
 - 9 Q. I think you mentioned a few in your
 - 10 report.
 - 11 A. Correct. And again, chronic inflammation
 - 12 is a very good term, but it is frequently misused
 - 13 because there are many types of chronic
 - 14 inflammation. There's chronic inflammation that
 - 15 causes cell death in tissues, and there's chronic
 - 16 inflammation that does very little in tissue, or
 - 17 practically nothing. So those are two very
 - 18 different types of chronic inflammation.
 - 9 Q. Which type of chronic inflammation would
 - 20 include the reactive oxygen species being released
 - 21 in an amount that would damage DNA and cause
 - 22 improper replication?
 - 23 A. Again --

24

- MR. HEGARTY: Objection, form.
- 25 THE WITNESS: Again, reactive oxygen

- 1 species damaging DNA have been shown only in cell 2 culture. So there hasn't been shown to -- have not
- 3 been proven in live organisms. The type of
- 4 inflammation that causes cancer is long-term
- 5 destructive inflammation.
- 6 BY MR. DEARING:
- 7 Q. Long-term destructive, that's what
- 8 chronic means; right?
- 9 A. No, chronic means that it's not acute.
- 10 It means that it's been there for a long time.
- 11 Q. Okay. Is chronic, as you're using it,
- 12 does that mean that it's an ongoing process?
- 13 A. That is correct.
- 14 Q. And I think we're using it the same way.
- 15 A. I don't think so.
- 16 Q. We'll see. Well, you would agree with
- 17 me, wouldn't you, that there are many credentialed
- 18 scientists who do believe that chronic inflammation
- 19 can cause cell damage that results in
- 20 carcinogenesis?
- 21 MR. HEGARTY: Objection to form.
- THE WITNESS: All of us believe that.
- 23 BY MR. DEARING:
- Q. Do you believe that there are reputable
- 25 scientists that believe that that occurs in the

	Page 70		Page 72		
1	female reproductive tract and, in particular, the	1	the talcum powder?		
	ovaries and fallopian tube?	2	MR. HEGARTY: Objection to form.		
3		3 THE WITNESS: Yes.			
4		4 BY MR. DEARING:			
5	physicians who believe that there are some types of	5 Q. Do you have any opinions about whethe			
6	inflammatory processes that increase the risk of	6 Johnson's baby powder has ever contained asbes			
	cancer such as pelvic inflammatory disease or upper	7 A. I have read reports that it found			
8	genital tract infection, has a slight association	8 asbestos in talcum powder.			
1	with increased ovarian cancer.	9 Q. Do you have any opinions yourself as t			
10	BY MR. DEARING:	10 whether the product has contained asbestos in			
11	Q. Would you agree with me that some studies	11	past? And I'm only saying the past, because it's		
12	do demonstrate a statistically significant increase	12	not on the market now. So at any time.		
13	of ovarian cancer of women who use talc in the	13	A. Because of those reports that have been		
14	genital area?	14	done, yes, they it probably did contain trace		
15		15	amounts of asbestos.		
16	THE WITNESS: There are cohort studies	16	Q. Have you ever seen any testing results		
17	that arrive at that conclusion.	17	from those tests testing the product for asbestos?		
18	BY MR. DEARING:	18	A. I have not witnessed the the testing		
19	Q. Do you agree that if talc were to reach	19	results personally, no.		
20	the fallopian tube or ovaries, that you would	20	Q. So when you say you have read reports,		
21	expect some type of inflammatory reaction by the	21	are you talking about reports that were just in the		
22	ovary or fallopian tube tissue?	22	general		
23	A. By necessity, yes.	23	A. In summaries		
24	Q. And would you agree that if the	24	Q media?		
25	inflammatory response could not adequately	25	A. In summaries like IARC.		
	Page 71		Page 73		
1	remediate the exposure, that the inflammatory	1	Q. Okay. Did you ever I'm sorry.		
2	response could become chronic, in other words,	2	You testified a while ago that you've		
3	long-term and ongoing?	3	not seen any Johnson & Johnson documents other tha		
4	MR. HEGARTY: Objection to form.	4	the ones that have been shown to you during		
5	THE WITNESS: The foreign body reaction,	5	cross-examination, either in a deposition or trial.		
6	which is the form of chronic inflammation that you	6	But did you ever ask to see any documents from		
7	expect with talc, would be ongoing for a very long	7	Johnson & Johnson?		
8	time.	8	A. No, I did not.		
9	BY MR. DEARING:	9	Q. So if it was established that Johnson's		
10	Q. And scientists and physicians refer to	10	baby powder did in fact have asbestos in it, is it		
11	that ongoing response, or that ongoing process, as	11	still your opinion that it's safe for women to use		
12	a chronic inflammation; right?	12	in the perineum?		
13	MR. HEGARTY: Objection to the form.	13	MR. HEGARTY: Objection to form.		
14	THE WITNESS: A chronic foreign body	14	THE WITNESS: Yes.		
15	inflammation.	15	BY MR. DEARING:		
16	BY MR. DEARING:	16	Q. What if it was established that the		
17	Q. Just making sure I'm using it correctly.	17	talcum powder had carcinogenic heavy metals like		
18	Words matter, so I want to get them right.	18	chromium or nickel or arsenic or lead or all of		
19	A. Sure.	19	them, would that affect your opinion about whether		
20	Q. So is it your opinion that Johnson's	20	talcum powder is safe to use in the genital area?		
21	talc-based baby powder is completely safe for women	21	MR. HEGARTY: Objection to form.		
22	to use in the perineum?	22	THE WITNESS: No. And may I please		
23	A. Yes.	23	explain it?		
24	Q. And is your opinion about Johnson's baby	24	BY MR. DEARING:		
25	more don without morand to anything that may be in	25	O Of acuma		

25

Q. Of course.

25 powder without regard to anything that may be in

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1 A. There is a minimum level of exposure that 2 must be exceeded before something is unsafe. So

3 cosmic radiation, which we are being blasted with

- 4 right now, is highly carcinogenic. Actually flight
- 5 attendants have a four-fold increase in breast
- 6 cancer because they're -- they don't have the
- 7 atmosphere to protect from many hours each day.
- You and I are being affected by it but
- 9 it doesn't increase our risk of cancer. Similarly,
- 10 if they take your lungs or part of your bladder and
- 11 they grind it up and look for asbestos, they will
- 12 find it. There is a base exposure that we are all
- 13 constantly exposed to that makes us inhale
- 14 asbestos.
- 15 There's -- there's probably -- we can
- 16 detect lead in your body if we looked hard enough.
- 17 But it's not going to affect you because it's in
- 18 such small amounts. Even plutonium, if in small
- 19 enough amount, will not adversely affect you. So
- 20 those are the reasons why I don't believe that any
- 21 of those things, if they find minimal trace amounts
- 22 of talcum powder, would be adverse to your health.
- Q. Well, would you agree with me that
- 24 regulatory agencies have stated that there is no
- 25 safe level of exposure to asbestos?
- Page 75
- MR. HEGARTY: Objection to form. 1
- THE WITNESS: Well, if a regulatory 2
- 3 agency said that, then they don't look at the
- 4 science. Because we all have asbestos in our
- 5 bodies. And as a matter of fact, they -- when you
- 6 do asbestos studies, you compare it to the -- to
- 7 the base background level of asbestos to see if
- 8 it's elevated.
- 9 BY MR. DEARING:
- Q. So do you disagree with the statement
- 11 that there is no safe level of exposure?
- 12 A. Yes, I disagree with that statement.
- Q. Is there some level of asbestos and
- 14 talcum powder that would change your opinion about
- 15 the safety of powder applied to the genital area
- 16 for women?
- 17 MR. HEGARTY: Objection to form.
- 18 BY MR. DEARING:
- Q. For example, if one percent of the
- 20 contents of a bottle of Johnson's baby powder was
- 21 chrysotile or tremolite asbestos, would your
- 22 opinion still be that talcum powder was safe for
- 23 women to use in the perineum?
- MR. HEGARTY: Object to the form. Calls
- 25 for speculation.

- THE WITNESS: Yeah. I mean, it's a crazy
- 1 2 question. The levels of asbestos detected in
- 3 talcum powder are parts per million, not
- 4 percentages. So it's -- it's just a -- it's a
- 5 theoretical assumption that I wouldn't know how to
- 6 approach.
- 7 BY MR. DEARING:
- 8 Q. It is a hypothetical for sure. So you
- 9 don't know what your answer would be if it were
- 10 established that one percent of the contents of a
- 11 Johnson's baby powder bottle contained asbestos?
- 12 MR. HEGARTY: Objection, form.
- 13 THE WITNESS: I have no idea what
- 14 asbestos on the skin would do. I don't -- I don't
- 15 know that. So I can't have an opinion about it.
- 16 BY MR. DEARING:
- Q. Well, is it your opinion that talcum 17
- 18 powder applied to the perineum cannot enter the
- 19 vagina?
- 20 A. Likely not in clinically significant
- 21 amounts, no.
- 22 Q. Can you quantify what you mean by
- 23 clinically significant amount?
- 24 A. Well, I mean if -- if -- if talcum powder
- 25 hit the mucosa of the vagina, it would likely do

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- 1 nothing there because the squamous epithelium would
- 2 not allow entry of the talc into the submucosa.
- 3 From examining tens of thousands, hundreds -- maybe
- 4 reaching 100,000 cervixes, endometrium, fallopian
- 5 tubes and ovaries, I don't find it there. So I
- 6 know that it doesn't go there in a quantity
- 7 sufficient to elicit a reaction.
- Q. Would that be true also if there were
- 9 asbestos fibers that were applied to the perineum
- 10 and it reached the internal structures of the
- 11 vagina?
- 12 A. Well, my experience is the same. I have
- 13 not seen asbestos in cervix, endometrium, fallopian
- 14 tubes or ovaries.
- 15 Q. Well, hypothetically then, if asbestos
- 16 were in the powder that was able to be introduced
- 17 in the vagina, wouldn't you expect there to be some
- 18 kind of reaction to the asbestos?
- A. No, because the asbestos would have to
- 20 get into the submucosa. That's why -- that's why
- 21 you --
- 22 Q. Tell me where, anatomically, the
- 23 submucosa is that you're referring to.
- 24 A. Certainly. So --
- 25 Q. Actually, I have a document. I finally

20 (Pages 74 - 77)

Page 78 Page 80 1 get to mark an exhibit. Exhibit 1. Sorry, this is 1 little bit of bleeding, and that's the submucosa. 2 probably elementary to you, but I'm still learning 2 That's where all the blood vessels that 3 it. 3 feed -- keep the mucosa healthy are. 4 So I'm marking as Exhibit 1 what I 4 So -- so the -- squamous epithelium is 5 believe is an anatomic diagram of the female 5 the epithelium that we all have that's very 6 reproductive tract. Does that look like an 6 protective. It's designed to be tough, not let 7 accurate diagram? 7 things come out of the body or not let things get A. It's an adequate representation of the 8 into the body. That's why you can take a shower 9 genital tract, yes. 9 and not bloat, right, because the skin doesn't let 10 Q. Is it accurate? I mean --10 the water go inside of you. The same thing with 11 MR. HEGARTY: Objection to form. 11 the vagina. It protects. It doesn't allow things 12 BY MR. DEARING: 12 to get inside of the body. 13 Q. As far as diagrams go. I know in the 13 Q. Okay. But we do know things get inside 14 body things are different, but --14 the body from the vagina; right? A. It shows the structures in a -- in an 15 15 MR. HEGARTY: Objection to form. 16 adequate way. 16 THE WITNESS: Yes, but -- but not into Q. Okay. I just have to prove --17 17 the vagina itself. Not into the submucosa of the 18 A. The ovaries --18 vagina. You're referring to the travel up the 19 Q. -- in order to use it, I have to prove 19 genital tract. 20 that it adequately represents what it says it 20 BY MR. DEARING: 21 represents. So does that adequately represent an 21 Q. Well, sure, so I'm just thinking -- I 22 image of the female reproductive tract? 22 mean, sperm, obviously, doesn't get trapped in the 23 A. Yes. 23 mucosa. 24 Q. Now tell me what mucosa you're referring 24 A. Correct. 25 to. Where is that? 25 Q. It's able to travel all the way to the Page 81 A. The mucosa is the dark pink colored part 1 fallopian tube to the uterus. 1 2 of the drawing here --2 A. Correct. 3 Q. Okay. Q. And also as I understand it -- we may A. -- of the vagina. The submucosa in the 4 4 talk more about it in a little while -- in the case 5 of endometriosis, do you agree that endometriosis 5 cut section would be the lighter pink. MR. DEARING: Let me mark a second 6 primarily occurs when uterine tissue is sloughed 7 diagram as Exhibit 2. 7 off or somehow removed and travels the same path 8 BY MR. DEARING: 8 through the fallopian tube and implants on the Q. So this is a cross-section of the 9 ovary? 10 anatomy. Would you agree that that's an accurate 10 MR. HEGARTY: Objection to form. 11 depiction of the cross-section of the female 11 THE WITNESS: That is the leading 12 reproductive tract? 12 hypothesis for endometriosis. 13 13 BY MR. DEARING: A. Yes. Q. Okay. Does that show the mucosa that 14 14 Q. And the mechanism or the -- the --15 you're talking about? 15 obviously uterine epithelium doesn't have motility, 16 so it has to get there somehow. Is that by 16 A. Yes. 17 Q. Okay. Can you show me in that diagram? 17 retrograde menstruation, in your opinion? 18 A. It is the one that's pointing by vagina. 18 MR. HEGARTY: Objection to form. 19 Q. Okay. 19 THE WITNESS: Retrograde menstruation A. The best way to show you the equivalence 20 20 caused by uterine contraction, yes. 21 is if you just touch the inside of your cheek, 21 BY MR. DEARING: 22 that's like touching the mucosa of the vagina. 22 Q. And so would you also agree that -- well, 23 23 that the uterine tissue that sloughs off -- is that Q. Okay. 24 A. Okay? And then the submucosa you would 24 the right medical term? What happens to that?

25

A. It is a slough-off.

25 have to scrape the lining off, which would cause a

Page 82 Page 84 Q. Okay. 1 tissue was vital. 1 2 A. It's a --Q. Well, you agree that there are published 3 Q. Does it get trapped in the mucosa 3 studies that show talc in ovarian and fallopian 4 as -- the vaginal mucosa as well, or is it able to 4 tube tissue that are within macrophages that are --5 pass through that? I know it's already above it, A. No. 6 but --6 Q. -- published in the literature. 7 7 A. It will not be able to penetrate the A. Nope. 8 vaginal mucosa. 8 MR. HEGARTY: Objection to form. Q. Okay. So I'm not sure why we're talking 9 THE WITNESS: Not in ovary or fallopian 10 about the vaginal mucosa. 10 tube. If they are published studies that show it A. Because -- because I don't see talc 11 in a lymph node in the pelvis, but not in the ovary 12 anywhere in the genital tract. And I look at 50 12 or fallopian tube. 13 samples a day. 13 BY MR. DEARING: Q. Oh, I see. Okay. Well --Q. How, in your opinion, did the talcum get 15 A. You asked me initially --15 to the pelvic lymph nodes? 16 A. Well, they didn't show that it was talc, Q. Right. A. -- if I thought that talc from the 17 17 by the way. They just saw particles within 18 perineum could get into the vagina. And I said not 18 macrophages of a lymph node. There is no evidence 19 in clinically significant ways. But if you put 19 that those particles were talc. 20 talc in the vagina, it wouldn't do anything because 20 So how do particles get into a lymph 21 node, into a pelvic lymph node? They can go in 21 the squamous epithelium is protective. It wouldn't 22 let the talc go into the body there. Does it go up 22 through abrasion to the perineum, an abrasion in 23 the genital tract? The answer is no. 23 the upper thigh. 24 Q. So if talc were to be introduced into the (Exhibit 3 marked for identification.) 25 vagina and could pass the mucosa, would you expect 25 BY MR. DEARING: Page 83 1 it to be able to travel through the fallopian tube Q. I'm showing you what's been marked as 2 much the way endometrial tissue does during 2 Exhibit 3, which is a study by Dr. Sandra McDonald 3 retrograde menstruation? 3 and other folks. And you cite this study in your 4 MR. HEGARTY: Objection to form. 4 report. And you cite it actually in all of your 5 THE WITNESS: I would not expect it to do 5 reports, specifically where you make the same 6 statement. Let me find it. It's in the paragraph 6 that. 7 BY MR. DEARING: 7 above the observational data paragraphs. And you 8 state --Q. Why wouldn't it?

9 A. Page?

10 Q. Well, I'm looking at the Carl report.

11 A. Yes. Oh, okay.

12 Q. The Carl report. But you say it in all

13 of your reports.

14 A. Okay.

15 Q. So the study we're referring to is called

16 Migration of Talc From the Perineum to Multiple

17 Pelvic Organ Sites, five case studies with

18 correlative light and scanning electron microscopy

19 by Dr. McDonald and five other physicians and

20 scientists, right? And it was published in the

21 American Journal of Clinical Pathology in 2019.

22 And you cite to this in every one of your reports;

22 1 1 10

23 right?

24 A. Yes.

Q. And you cite to it behind the sentence

- 9 A. Because if it did, I would see it. I
- 10 don't see it. Nobody else sees it either. Nobody
- 11 reports talc in tissues of the genital tract. I
- 12 don't find a single report in the world literature
- 13 about talc being present in tissues of the genital
- 14 tract. Now I'm not talking about --
- 15 Q. You actually cite studies that show that.
- MR. HEGARTY: Let him finish his answer.
- 17 Were you finished?
- 18 BY MR. DEARING:
- 19 Q. I'm sorry. I didn't mean to cut you off.
- A. I know that there are people who grind up
- 21 the tissues of the genital tract and find talc. I
- 22 know that there are people who do SDS whatever
- 23 testing on -- on -- on tissue blocks that claim
- 24 that they find -- and they do probably find -- some
- 25 talc. But it wasn't there when the -- when the

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- 1 that says, "Studies reporting talc particles in
- 2 gynecologic tissue are also unconvincing as they
- 3 fail to corroborate their findings with the
- 4 expected histological response to talc, which is
- 5 necessary to rule out specimen contamination as a
- 6 likely alternative explanation to their findings."
- 7 And then you testified just now that
- 8 not a single report has demonstrated talc in
- 9 macrophages in the ovaries or lymph nodes.
- 10 A. I said ovaries or fallopian tubes.
- 11 Q. Or fallopian tubes. I'm sorry. So first
- 12 of all, are you familiar with this study?
- 13 A. Yes.
- 14 Q. You've obviously read it because you cite
- 15 it in every report; right?
- 16 A. Yes, I'm very familiar with it.
- 17 Q. Okay. If you would -- well, the
- 18 objective of this study, as stated in the abstract,
- 19 says that genital talc use is associated with
- 20 increased risk of ovarian carcinoma in
- 21 epidemiologic studies. Finding talc in pelvic
- 22 tissues in women with ovarian carcinoma who have
- 23 used talc is important in documenting exposure and
- 24 assessing talc's biologic potential, but
- 25 tissue-based morphology studies have been rarely

- Page
- 1 Q. I know SEM is not your expertise, but you 2 agree that SEM with EDX capability can identify
- 3 particles like talc?
- 4 MR. HEGARTY: Objection to the form.
- 5 THE WITNESS: It can identify that
- 6 they're in the proper ratio, which the person who
- 7 does this is just Dr. Godleski, gives himself a
- 8 five percent wiggle room. Remember what I said,
- 9 biology's not physics.
- 10 BY MR. DEARING:
- 11 Q. Right.
- 12 A. This is physics. If the thing doesn't
- 13 hit it perfectly, then you're not sure that it's
- 14 talc.
- 15 Q. Well, you would agree with me that five
- 16 percent -- actually ten percent -- is accepted in
- 17 particle identification, a ten percent variance?
- 18 A. By whom? Accepted by whom?
- 19 MR. HEGARTY: Objection.
- 20 BY MR. DEARING:21 Q. By experts in the field of particle
- 22 identification.
- 23 MR. HEGARTY: Objection to form.
- 24 THE WITNESS: I -- again, I'm not an
- 25 expert in the area, so I'm not going to -- I'm not

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1 reported.

- 2 And then the method is important.
- 3 Because they say we report five patients -- I'm
- 4 sorry -- five patient cases with documented
- 5 perineal talc exposure or use, each of whom had
- 6 talc both by polarized light and scanning electron
- 7 microscopy in multiple pelvic sites distant from
- 8 the perineum.
- 9 And then the results state, "Talc
- 10 particles were found in exposed patients typically
- 11 within two or more of the following locations:
- 12 pelvic region lymph nodes, cervix, uterine corpus,
- 13 fallopian tubes, and ovaries."
- 14 And then I want to direct your
- 15 attention specifically to image 4C, which is on
- 16 page -- and incidentally, as the authors describe,
- 17 the talc particles were studied not just by
- 18 polarized light and microscopy, but by scanning
- 19 electron microscopy with EDX, energy-dispersive
- 20 x-ray spectroscopy, I think is how you pronounce
- 21 that. Anyway, the point is, it's a process by
- 22 which talc particles can be definitively
- 23 identified; right?
- MR. HEGARTY: Object to the form.
- 25 BY MR. DEARING:

- 1 going to -- to absolutely say that it's not
- 2 accurate. But in my opinion, if you are saying
- 3 that something is a mineral, an exact mineral, that
- 4 mineral should be spot on in its composition, not a
- 5 little bit.
- 6 BY MR. DEARING:
- 7 Q. Well, let's -- hold that thought. Let's
- 8 talk about this study.
- 9 A. Okay.
- 10 Q. Then I'll come back to that, okay?
- 11 'Cause that's an important point. But for purposes
- 12 of these questions, unless you're going to say this
- 13 is not talc that he's finding, I want to ask you
- 14 specifically about image 4C. Are you able to find
- 15 it yet?
- 16 A. Yeah, I have it.
- 17 Q. It says, "Scanning electron microscopy,
- 18 SEM, at 500 times magnification with back-scattered
- 19 electron imaging from the same general area as in A
- 20 and B in that same image, but a different
- 21 histologic section showing numerous back-scattered
- 22 electron-positive particulates within the cytoplasm
- 23 of macrophages similar to A, the majority of which
- 25 So would you agree with me that at

24 has a spectrum characteristic of talc."

Document 33002-6 PageID: 197208 Page 90 1 least in that image, these scientists are saying A. A scanning electron microscopy looks only 2 they have identified talc within the cytoplasm of 2 at the surface. It cannot look below the surface 3 macrophages in that tissue? 3 of the tissue. 4 MR. HEGARTY: Object to form. Q. Actually, a variable pressure SEM does THE WITNESS: Okay. In the -- in the H 5 look below the surface of the tissue. 6 and E section, which is 4E, I will agree that those 6 MR. HEGARTY: Objection. 7 particles are within macrophages. In the SEM, 7 BY MR. DEARING: 8 which is F, you can't tell those particles are in 8 Q. Do you know what a variable pressure SEM 9 macrophages. 9 is? 10 BY MR. DEARING: 10 MR. HEGARTY: Objection to the form. Q. Which image are you looking at? I'm 11 11 THE WITNESS: I am not. 12 looking at --12 BY MR. DEARING: 13 A. This one. 13 14 Q. -- four --15 A. Four? 16 O. C. 16 17 A. Oh. 17 Q. 4C is where I'm starting. We'll get to 18 that. 19 the others. But 4C is where I'm starting. That's 19 BY MR. DEARING: 20 where I just read from. 20 21 A. Right. So 4C, you can't tell that that's 22 a macrophage. Q. Well, the scientists thought they could

THE WITNESS: Well, they --1 2 BY MR. DEARING: 3 Q. So you disagree with the scientists that 4 published this paper? They're saying it's a 5 macrophage and they're wrong? A. I -- I say that they can't tell that 7 those particles are inside a macrophage. Q. Well, you would -- would you agree with 9 me that you're not an SEM expert? 10 A. I am not. 11 Q. An expert in scanning electron 12 microscopy? A. I'm not an expert. 13 Q. Would you also agree with me then, or do 14

24 tell it was a macrophage. They published in --24 MR. HEGARTY: Objection to form. Page 91 15 you know, that when you're actually looking through 16 the -- when you're actually looking at the SEM 17 image on the computer, that it looks different than 18 the two-dimensional photograph you're looking at in 18 MR. HEGARTY: Objection to form. THE WITNESS: It does not, because SEM is 22 a two-dimensional mode of viewing tissue. You are 22 23

Q. Okay. Do you know that Dr. Godleski and 14 his team are using variable pressure scanning 15 electron microscopy to make these observations? MR. HEGARTY: Objection to form. THE WITNESS: I am completely unaware of Q. Okay. But it's your opinion that these 21 authors got this wrong and that those -- those 22 particles that they are saying in image 4C are in 23 the cytoplasm of a macrophage are not? A. Well, they -- they might be, but they 25 can't say that because it's a two-dimensional mode Page 93 1 of evaluating the tissue. And by the way, 2 the -- Dr. Godleski finds more non-talc particles 3 than talc particles in every single --4 Q. True. A. -- study that they make. 5 Q. True. He doesn't hide that. In every 7 report he issues he identifies everything. A. So statistically it's more likely those 9 particles that we see in the H&E slides are not 10 talc. They're something else. Q. I understand. But the particles he's 12 identified by scanning electron microscopy, which 13 he says is in these macrophages, he is saying is 14 talc. Well, not him, the authors, Dr. McDonald and 15 Dr. Fan. By the way, do you know Dr. Fan, the 16 microscopist from Brown? 17 A. I don't. MR. HEGARTY: Objection to form. 19 BY MR. DEARING: Q. Do you know Dr. Welch? He's a gyn -- was 20 21 a gyn pathologist. A. I knew him, yes. Q. Okay. And you know who Dr. Dave Cramer 24 is; right? 25 A. Yes.

24 (Pages 90 - 93)

20

25

19 a published paper; right?

23 only looking at the surface.

Q. So it's your --

24 BY MR. DEARING:

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- 1 Q. If you would also look at image 4F, which
- 2 is in the next page, I think. Yep. And the
- 3 authors there say that SEM from the same general
- 4 area as D and E, but in a different -- different
- 5 histologic section, showed numerous back-scattered
- 6 electron-positive particulates within the cytoplasm
- 7 of macrophages similar to C, and the majority
- 8 having a spectrum characteristic of talc.
- 9 Is it your opinion that those
- 10 images -- that the image 4F is not showing
- 11 particles in a mac -- in macrophages?
- 12 A. I'm saying that the mode of examining it
- 13 can't definitively say that, no. Yeah, that's what
- 14 I'm saying.
- 15 Q. So you think that, although you're not an
- 16 expert in the field of scanning electron
- 17 microscopy, that you know more about this or you're
- 18 able to make more accurate observations than the
- 19 experts in the field of scanning electron
- 20 microscopy?
- 21 MR. HEGARTY: Objection to form.
- THE WITNESS: I can give you my opinion.
- 23 BY MR. DEARING:
- Q. Okay. So as I understand it, you're not
- 25 saying they're wrong, you're just saying they can't
 - Page 95
 - 1 tell. Is that what you're saying?
- 2 MR. HEGARTY: Objection to form.
- 3 THE WITNESS: Correct.
- 4 BY MR. DEARING:
- 5 Q. Okay. You think that the American
- 6 Journal of Clinical Pathology is a reputable
- 7 journal, don't you? You've published in it,
- 8 haven't you?
- 9 A. I'm very close friends with the editor in
- 10 chief.
- 11 Q. Right. It's one of the best journals in
- 12 the field, isn't it?
- 13 A. It's -- it's highly regarded.
- 14 Q. And of course this is a peer-reviewed
- 15 publication; right?
- 16 A. Yes.
- 17 Q. Which means other peers in the specialty
- 18 of the authors have reviewed this paper before it
- 19 was allowed to be accepted to be published; right?
- 20 A. Yes.
- Q. Would you also look at image 5H? There
- 22 the authors write, again, another example of
- 23 particulates within the cytoplasm of macrophages.
- 24 A. Same answer.
- Q. And is it your opinion that you don't

- ch 1 know whether those particles are within a
 - 2 macrophage?
 - 3 A. Correct.
 - 4 Q. But you agree with me that the authors
 - 5 and the experts in the scanning electron microscopy
 - 6 state that they are?
 - 7 MR. HEGARTY: Objection to form.
 - 8 THE WITNESS: They do state that, yes.
 - 9 BY MR. DEARING:
 - 10 Q. And then would you look at image 7D? And
 - 11 again, the authors write that this image shows
 - 12 numerous backscattered electron-positive particles
 - 13 within the cytoplasm of a macrophage.
 - 14 A. Same answer.
 - 15 Q. Okay. Looking at 7D and the way those
 - 16 particles are aligned in sort of a uniformed,
 - 17 encompassed fashion, doesn't it appear to you that
 - 18 those are macrophage because of the way they are
 - 19 and they're not just scattered amongst the tissue?
 - 20 MR. HEGARTY: Objection to form.
 - THE WITNESS: There are many images that
 - 22 have been offered by these authors, both H&E and
 - 23 SEM, that appear aggregated but not within the
 - 24 cytoplasm of the cell in the H&E. And I -- so I
 - 25 can't tell.

21

Page 97

- 1 BY MR. DEARING:
 - Q. Well, let me ask you this. Whether you
 - 3 can tell definitively or not, doesn't the image in
 - 4 7D at least look like particles in a macrophage?
 - 5 Isn't that what you would expect it to look like?
 - MR. HEGARTY: Objection to form.
 - 7 THE WITNESS: I -- I -- so if you look at
 - 8 the H&E images -- so if you look at 4B, one of
 - 9 those cells is a macrophage and clearly has
 - 10 particles in its cytoplasm.
 - 11 BY MR. DEARING:
 - 12 O. Which one?
 - 13 A. Yes, I have it -- I gave you the wrong
 - 14 image.
 - 15 Q. I agree with you on 4B, but --
 - 16 A. No, it was -- it's -- I mean, it -- the
 - 17 magnification on some of these is just too small
 - 18 for me to see. So there are images in here where
- 19 you have particles in macrophages, mainly in the
- 20 lymph node. It's not surprising. The lymph node
- 21 is where all the small particles are taken.
- 22 Q. Okay. So back to what started this
- 23 dialogue was you made the comment that there are no
- 24 publications that show talc in the macrophages of
- 25 ovarian and fallopian tube tissue; right?

25 (Pages 94 - 97)

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	Page 98		Page 100			
1	A. I said	1 statement that I just read about in your report,				
2	MR. HEGARTY: Objection to form.	2 you say, "Studies reporting talc particles in				
3	THE WITNESS: no reports of foreign	3 gynecologic tissues are also unconvincing as th				
	dy reaction to talc in ovaries or fallopian	4 fail to corroborate their findings with the				
5 tub	-	5 expected histological response to talc, which				
	Y MR. DEARING:	6 necessary to rule out specimen contamination				
7	Q. So it's not that that hasn't been	7 likely alternative explanation for their findin				
	ported in the literature, it's that you don't	8 And you cite McDonald 2019 in				
_	cessarily agree with what their opinions are in	9 Ultrastructural Pathology. Well, first of all,				
1	e published literature; right?	10 McDonald 2019 in Ultrastructural Patholog				
11	MR. HEGARTY: Objection to form.	11 even about what that sentence, is it? This is				
12	THE WITNESS: They don't show the right	12 copy of that study.				
	action to talc. They're they're basically	13 And if you recall, in that study, the				
1	king particles that are likely contaminants, that	14 scientists looked at Johnson's baby powder und				
1	e in the surfaces of the ovary and tube, or	15 scanning electron microscope to discern what				
1	rineum they don't even have it in the ovary	16 variations were in the magnesium and silicon				
_	elf. They say adjacent tissue and they're		ratios. And they determined that a .05 percent, or			
	ying that that is evidence that there	18 .05 or a five percent variance, is conservative, t				
1	as that there was migration of talc. I	19 say the least, in determining whether the particl				
1	sagree with this paper, and I disagree with their	20 are talc. Do you remember that from that study				
	nclusions.	21 MR. HEGARTY: Objection to form.				
22 BY	Y MR. DEARING:	22 THE WITNESS: I'm sorry, I have to rea				
23	Q. But the statement that there are no	23 it.				
24 pu	blications that demonstrate that	24 BY MR. DEARING:				
25	A. That demonstrate the foreign body	25 Q. Take your time.				
	Page 99		Page 101			
1 rea	Page 99 action. They don't show a foreign body reaction	1	Page 101 A. Yes, the authors themselves say is			
1 rea	action. They don't show a foreign body reaction	1 2	A. Yes, the authors themselves say is			
	action. They don't show a foreign body reaction re.		A. Yes, the authors themselves say is reasonably close. So, I mean			
2 hei 3	nction. They don't show a foreign body reaction re. Q. Okay. Well, you just said that there's	2	A. Yes, the authors themselves say is reasonably close. So, I mean Q. What is reasonably close?			
2 hei 3 4 an	nction. They don't show a foreign body reaction re. Q. Okay. Well, you just said that there's H&E slide photo micrograph that shows particles	3 4	A. Yes, the authors themselves say is reasonably close. So, I meanQ. What is reasonably close?A. That's what they state. This standard			
2 hei 3 4 an	ection. They don't show a foreign body reaction re. Q. Okay. Well, you just said that there's H&E slide photo micrograph that shows particles a macrophage.	2 : 3 : 4 : 5 : 5 : 6	A. Yes, the authors themselves say is reasonably close. So, I mean Q. What is reasonably close?			
2 her 3 4 an 5 in a	nction. They don't show a foreign body reaction re. Q. Okay. Well, you just said that there's H&E slide photo micrograph that shows particles	2 3 4 5 6	A. Yes, the authors themselves say is reasonably close. So, I mean Q. What is reasonably close? A. That's what they state. This standard deviation, da, da, da, da, the current use, plus or			
2 her 3 4 an 5 in 6	nction. They don't show a foreign body reaction re. Q. Okay. Well, you just said that there's H&E slide photo micrograph that shows particles a macrophage. A. In a lymph node, yes.	2 3 4 5 6	A. Yes, the authors themselves say is reasonably close. So, I mean Q. What is reasonably close? A. That's what they state. This standard deviation, da, da, da, da, the current use, plus or minus five percent diagnostic range, is thus			
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Q. I wish you had led with that. We're not

25 arguing. I just want to make sure we're being

24 you to another study that you cited in every one of

25 your reports, in the same string cite, to the

Page 102 Page 104 1 accurate here. But you cite that for this 1 it. 2 proposition in your report about studies reporting 2 BY MR. DEARING: 3 talc particles in gynecologic tissues are Q. Okay. 4 unconvincing and fail to corroborate their 4 A. Off the top of my head. 5 Q. It's a study I'd like to forget. 5 findings. But this study doesn't really address 6 that statement, does it? 6 A. Yeah. 7 MR. HEGARTY: Objection to form. 7 Q. Because it blows my mind. In this 8 BY MR. DEARING: 8 McDonald study and lots of others, one of the Q. I mean, you can disagree with me, but --9 things they discussed here is the morphology of 10 A. I'd rather not. 10 talc. Are you familiar with the different Q. You know what, I'll withdraw that 11 morphologies of talc, in other words, that talc is 12 question. It's not necessary. You don't have to 12 found in both a plate form and a fibrous form? MR. HEGARTY: Objection, form. 13 spend time on it. 13 14 14 THE WITNESS: I am familiar with that, I will point out one other cite of 15 that list of studies. For that same proposition 15 yes. 16 you cite Campion 2018, and I don't have that with 16 BY MR. DEARING: 17 me. But if you'll recall, Campion 2018 was a Q. Have you ever looked at Johnson's baby 17 18 comparison of Raman's spectroscopy identification 18 powder under a microscope? 19 of talc with Dr. Godleski's SEM identification of A. I have not looked at Johnson's baby 20 talc, and found that they were identical. Do you 20 powder under a microscope. 21 remember that? 21 Q. Have you ever seen photomicrographs of 22 A. I don't --22 Johnson's baby powder under a microscope other than 23 23 those that are contained in this McDonald study? MR. HEGARTY: Objection to form. 24 THE WITNESS: -- off the top of my head. 24 A. I have seen representations of 25 BY MR. DEARING: 25 talc -- microscopic representations of talc, yes. Page 103 Page 105 Q. Do you know anything about Raman 1 And I have seen actual talc in tissues as well. 1 2 spectroscopy? 2 Q. I'm referring specifically to Johnson's 3 A. Very little. 3 baby powder, though. Have you seen Johnson's baby 4 Q. Do you understand that Raman spectroscopy 4 powder, the talc -- have you observed Johnson's 5 is probably the most precise way to identify a 5 talc-based baby powder under a microscope? 6 particle because it is able to identify the unique A. I have not. 7 way that the atoms are reacting to each other in a Q. We were talking about endometriosis, and 8 before that we were talking about macrophages. Let 8 unique signature that each different element has? MR. HEGARTY: Objection to form. 9 me ask you this. 10 BY MR. DEARING: 10 If endometrial cells were to slough Q. That's all I understand about it, so --11 off from the uterus, they'd be transported and 12 A. I think your description is about as 12 implanted on the ovary, or I guess even hung up in 13 the epithelial tissue of the fallopian tube, 13 vague as I would be able to --14 Q. Okay. 14 wouldn't that attract macrophages because it's a 15 15 cell that shouldn't be there -- or it's a tissue A. -- give it. Q. The point is, you cite Campion 2018. And 16 that shouldn't be there? 17 I'm asking, I guess, if you remember that that was 17 MR. HEGARTY: Objection to form. 18 a comparison study, sort of a proof of method 18 THE WITNESS: It does not need to attract 19 study, that compared SEM identification of talc in 19 macrophages, no. 20 this .05 variance and Raman spectroscopy 20 BY MR. DEARING: 21 21 identification of talc, and they -- and it Q. Does it occasionally attract macrophages? 22 established that the SEM was just as accurate as 22 A. Yes, if the endometriosis bleeds. 23 the Raman. Do you remember that about that study? 23 Q. Okay. I should have been more general. 24 MR. HEGARTY: Objection to form. 24 Does it attract any kind of inflammatory mediators,

25 whether lymphocyte, anything?

THE WITNESS: I actually don't remember

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- 1 A. Rarely. Most of the time it's just
- 2 sitting in the tissue.
- 3 Q. Isn't it true that endometriosis is a
- 4 condition that occurs when endometrial tissue is
- 5 sloughed off and then later implanted in parts of
- 6 the body that it doesn't belong, causing some kind 7 of reaction?
- 8 A. That is the favored hypothesis. There
- 9 are other hypotheses, but that is the favored
- 10 hypothesis and the mechanism that I believe causes
- 11 endometriosis.
- 12 Q. And what kind of reaction occurs when
- 13 those cells are displaced and implant somewhere
- 14 else?
- 15 A. The types of reactions are varied.
- 16 Sometimes you can't see a reaction at all, so you
- 17 just -- you're looking at the tissue and then you
- 18 run into an endometrial gland with stroma. The
- 19 tissue surrounding it maintains its normal
- 20 appearance, no inflammation, no deviance from its
- 21 normal appearance.
- Other times -- and this is
- 23 frequent -- you will be looking at tissue and find
- 24 the endometrial gland and endometrial stroma, and
- 25 there would be a fibrous reaction to it. So let's
 - Page 107
- 1 say that you found it in the pelvic adipose tissue,
- 2 fatty tissue of the pelvis. You will see adipose
- 3 tissue which is fat. And then you would get to the
- 4 endometriotic gland and it would be surrounded by
- 5 fibrous tissue which doesn't belong there.
- 6 Q. Is it the fibrous tissue that causes the
- 7 adhesions we were talking about earlier?
- 8 A. It is the reaction -- the fibrotic
- 9 reaction to endometriosis that causes adhesions.
- 10 Q. And does that endometrial tissue response
- 11 also occur on the ovary?
- 12 A. It does.
- 13 Q. You've opined that endometriosis is a
- 14 risk factor for endometrial carcinoma of the ovary.
- 15 How does it transition from endometriosis to
- 16 endometrioid carcinoma?
- 17 A. So it's a complex series of genetic
- 18 anomalies. Many, if not most endometriosis have
- 19 some of the same mutations that are found in
- 20 endometrial carcinoma. I believe it's ARIDA1 and
- 21 PIC3A mutations are frequently found in
- 22 endometriosis. Those are abnormal mutations that
- 23 are associated with cancer.
- So we know that for whatever reason,
- 25 this endometrium that is retrogradely menstruated

Page 10

- 1 onto the pelvis acquires these mutations which are
- 2 not normally seen in parietal endometrium in the
- 3 uterus.
- 4 So once you start getting accumulating
- 5 mutations, it's -- it's very easy to understand
- 6 that it will progress to carcinoma. Now, what
- 7 percentage of women with endometriosis develop
- 8 endometrioma carcinoma? Not close to half of them.
- 9 But some of them do.
- 10 Q. You mentioned that surgical glove
- 11 manufacturers stopped dusting their gloves with
- 12 talc decades ago because it was leaving talc inside
- 13 the body and causing inflammatory reactions. Are
- 14 you aware that the condom industry stopped dusting
- 15 condoms with talc decades ago as well for much the
- 16 same reason?
- 17 MR. HEGARTY: Objection to form.
- 18 THE WITNESS: Well, they stopped dusting
- 19 with talc, but not for the same reason.
- 20 BY MR. DEARING:
- Q. Why do you think the condom industry
- 22 stopped dusting their condoms with talc?
- A. I have no idea. I'm not an expert in
- 24 condoms.
- 25 Q. Would you expect condoms to introduce

Page 109

- 1 talc into the female reproductive tract if they 2 were dusted with talc?
- 3 A. I would not expect that to happen.
 - Q. That because you think the talc would not
- 5 escape the mucosa that you described before?
- 6 A. It would not go into the upper genital
- 7 tract.

- 8 Q. If talc could somehow reach the uterus,
- 9 would you agree that it could be transported the
- 10 same way endometrial tissue can be transported, and
- 11 implant on the ovaries --
- MR. HEGARTY: Objection to form.
- 13 BY MR. DEARING:
- 14 Q. -- to retrograde menstruation?
- 15 A. No. The ability of the female genital
- 16 tract to allow things into the -- into the upper
- 17 genital tract is extremely selective.
- 18 O. How so?
- 19 A. Well, to remain as a viable species, it
- 20 needs to allow sperm to go up. But --
- Q. But if it was extremely selective -- I'm
- 22 sorry. Go ahead. It shouldn't allow endometrial
- 23 tissue to go up because it's damaging.
- 24 A. Well, the endometrial's already up. It's
- 25 already in the cavity.

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Page 110 Q. Okay. A. There's no cervical barrier for that to 3 retrograde menstruate.

4 Q. Okay.

1

2

5 A. As you might be aware or not, but I'll 6 make you aware --

7 Q. Presume I'm not.

8 A. -- there are ten to the ninth to ten to

9 the twelfth bacteria in the vagina. The

10 endometrium is sterile. Why don't bacteria go into

11 the plump? Well, it's very selective, right? It

12 doesn't allow certain things to go up. One of the

13 things that it doesn't allow to go up would be

14 talc. Because hundreds of thousands of people use

15 talc, or used to use talc in their -- in their

16 perineal area, and we did not see talc granulomas

17 anywhere.

1

Q. I think the question is how does it

19 prevent the talc from going up, or how does it

20 prevent the bacteria from going up?

A. It is a wonderful biological process that

22 we can't explain. But what we do know is it

23 doesn't happen. I mean, you can't -- you can't say

24 that bacteria go into the endometrial cavity when

25 we know that the endometrial cavity is sterile.

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Q. Well, some viruses do, don't they?

2 A. And some bacteria occasionally do also.

3 Like gonorrhea is very good at that. But it

4 probably doesn't go up the cervix. It probably

5 goes around into the tissues. So, anyway, needless

6 to say, the genital tract wouldn't survive if

7 bacteria could go up the cervix.

Q. Okay. So your opinion is talc cannot

9 migrate from the vagina to the reproductive tract,

10 but you're not sure why?

11 MR. HEGARTY: Objection to form.

12 THE WITNESS: Correct. I haven't studied

13 it. I know -- I've read many animal studies that

14 have tried to -- to get talc to go up the upper

15 genital tract, and most of them have failed, even

16 though they inject it into the fornix and even into

17 the uterus.

18 BY MR. DEARING:

Q. Well, you agree there are some human

20 studies that actually show that carbon particles,

21 for example, were used that did migrate. You may

22 take exception to how they were introduced into the

23 body, but you would agree that there are at least

24 some studies that purport to show that particles

25 can migrate to the ovaries?

A. Some --1

> 2 MR. HEGARTY: Objection to form.

3 THE WITNESS: Some particles have been

4 shown to migrate.

5 BY MR. DEARING:

Q. Okay. You state in all these reports

7 that the talc found -- well, let me just ask you.

Isn't it true that if talc is found in a

9 macrophage, that cannot be the product of

10 contamination?

11 A. You are correct.

12 MR. HEGARTY: Objection to form.

13 BY MR. DEARING:

Q. I'm sorry about this. I don't remember 14

15 where we landed. Do you believe that environmental

16 factors can play a role in the development of

17 epithelial cancers?

18 MR. HEGARTY: Objection to form.

19 BY MR. DEARING:

20 Q. We started the conversation. I honestly

21 don't remember where we ended up.

22 A. Environmental factors. I think if

23 a -- the answer is no, I don't -- I don't believe

24 environmental factors. One of the things that I

25 was going to speculate was maybe ionizing

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1 radiation.

2 Q. Right.

A. But women are treated with radiation for

4 cervical cancer and they don't develop ovarian

5 cancer. So it's unlikely to happen.

Q. Do you agree that one of the protective

7 factors for ovarian cancer is tubal ligation?

8 A. Yes.

9 Q. What is your opinion as to how tubal

10 ligation is protective? Someone opined it prevents

11 environmental exposures from transversing the

12 fallopian tubes. But I assume you have a different

13 take?

14 MR. HEGARTY: Objection to form.

15 THE WITNESS: Oh, it could be many

16 reasons. It could -- for one thing, tubal ligation

17 arrests the motility of the fallopian tube. It

18 interferes with the motility of the fallopian tube.

19 Therefore it could -- it could possibly prevent

20 more tubal cells to enter the ovary. That's a

21 possible mechanism. I'm speculating now, because

22 I've not studied this. But it doesn't have to be

23 prevention of environmental factors from getting

24 into the ovary.

25 BY MR. DEARING:

Page	1	1	4
1 450	-	-	•

- 1 Q. Well, because of what you said about
- 2 environmental factors, you don't believe that
- 3 tubal ligation prevents environmental exposures
- 4 from -- from transversing the fallopian tubes
- 5 because they weren't doing that anyway; right?
- 6 MR. HEGARTY: Objection.
- 7 THE WITNESS: Correct.
- 8 BY MR. DEARING:
- 9 Q. So in your opinion the reason tubal
- 10 ligations are protective against ovarian cancer is
- 11 because a tubal ligation will prevent tubal cells
- 12 from transversing the fallopian tube and implanting
- 13 on the ovary or thereabout?
- 14 MR. HEGARTY: Objection to form.
- 15 THE WITNESS: I speculate --
- MR. HEGARTY: Go ahead.
- 17 THE WITNESS: I speculate that that may
- 18 be one of the factors, yes.
- 19 BY MR. DEARING:
- Q. Can you think of any other reason why
- 21 that might be protective?
- 22 A. I -- I cannot. And I have to confess I
- 23 haven't thought that much about it.
- Q. Would you agree with me that Blaustein's
- 25 pathology textbook, the pathology of the female

- Page 116
- 1 have four or five of them sitting on my shelf.
- 2 Q. What about other sources besides
- 3 textbooks? Where would you go to -- to research a
- 4 particular issue in GYN pathology?
- 5 A. I use the search engine PubMed on a daily
- 6 basis.
- 7 Q. Any other sources specifically that you
- 8 would consider reliable that you would go to for
- 9 questions you might have?
- 10 A. Not that I can think of. I mean,
- 11 Blaustein's is -- is very comprehensive and -- and
- 12 well edited throughout the years. So -- so I -- I
- 13 rely on it for most of the diagnostic issues that
- 14 come up that I have -- that I'm not completely
- 15 certain about.
- MR. DEARING: Okay. It's noon. Do you
- 17 guys want to keep going or take a short break for
- 18 lunch?
- 19 MR. HEGARTY: Probably take a short
- 20 break. Not for lunch, but it's time to take a
- 21 short break.
- 22 MR. DEARING: Okay.
- 23 (Break taken.)
- 24 BY MR. DEARING:
- Q. Doctor, let me switch gears a little bit.

- 1 genital tract, is an authoritative, reliable source
- 2 for female pathology issues?
- 3 MR. HEGARTY: Objection to form.
- 4 THE WITNESS: That's another term that
- 5 carries a lot of luggage, authoritative. So I
- 6 think it is -- I think that it is a respected
- 7 source of information. It is extremely 8 educational. It is the book -- the textbook that I
- 9 prefer to use to confirm my opinions on things,
- 10 yes.
- 11 BY MR. DEARING:
- 12 Q. Because there was an objection to that
- 13 question, let me ask it a different way.
- 14 What is your opinion -- I'm sorry, you
- 15 may just repeat yourself, but what is your opinion
- 16 about Blaustein's Pathology of the Female Genital
- 17 Tract?
- 18 A. I think it is a -- an excellent,
- 19 comprehensive textbook that is highly respected.
- Q. Are there any other pathology textbooks
- 21 that you would defer to if you had a question and
- 22 you feel like you need to do a little research?
- A. Sure, there's one by Oliva.
- Q. How do you spell that?
- A. O-L-I-V-A, that is quite good. Gosh, I

- Page 117
 1 Just a few more general topics, and then we'll move
- 2 on to specific cases. But I want to ask you some
- 3 questions about asbestos.
- 4 Do you intend to offer any opinions
- 5 about asbestos and whether it can contribute to
- 6 cause ovarian cancer?
- 7 MR. HEGARTY: Objection to form.
- 8 THE WITNESS: Yes. I intend to render
- 9 the opinion that asbestos does not cause epithelium
- 10 ovarian cancer.
- 11 BY MR. DEARING:
- 12 Q. Do you consider yourself an expert in the
- 13 field of asbestos?
- 14 A. I do not. I consider myself a
- 15 pathologist who's experienced in neoplasms caused
- 16 by asbestos.
- 17 Q. Have you ever published on any topics
- 18 associated with asbestos and the types of cancer
- 19 that it causes?
- A. I have not.
- Q. You agree that asbestos is a known human
- 22 carcinogen?
- A. I agree.
- Q. Have you ever lectured on
- 25 asbestos-related conditions?

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- A. I have not.
- 2 Q. Have you ever diagnosed anyone with an
- 3 asbestos-related condition?
- 4 A. Many times.
- 5 Q. Have you ever diagnosed anyone with
- 6 peritoneal mesothelioma?
- 7 A. Yes.

1

- 8 Q. And tell me, how do you define a
- 9 ferruginous body?
- 10 A. Ferruginous body is a microscopic
- 11 particle. It is long. When stained with
- 12 hematoxylin and eosin, it stains dark purple-black.
- 13 It has a geography to it, so usually it contains
- 14 wider areas interspersed with narrow areas
- 15 interspersed with wider areas. So it's -- and it's
- 16 a long particle.
- 17 Q. Does the way that a ferruginous body
- 18 forms depend on the morphology of the asbestos
- 19 fiber itself? In other words, ferruginous bodies
- 20 are formed around asbestos fibers; right?
- 21 A. Correct.
- Q. And so the shape of the ferruginous body,
- 23 for example, the morphology, is dependent upon the
- 24 shape of morphology of the asbestos fiber itself;
- 25 right?

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- 1 A. Yes.
- 2 Q. Do ferruginous bodies form wherever
- 3 asbestos is found in the body?
- 4 A. Yes.
- 5 Q. And they're called ferruginous bodies
- 6 because it's iron that actually forms around the
- 7 asbestos fiber; right?
- 8 A. Correct.
- 9 Q. Are ferruginous bodies birefringent?
- 10 A. No.
- 11 Q. Where all have you observed ferruginous
- 12 bodies in your career?
- 13 A. Where?
- 14 Q. Where, like what -- in what organs? I
- 15 know the lung, obviously.
- 16 A. The pleura.
- 17 Q. The pleura.
- 18 A. Have I seen it in lung? I don't remember
- 19 if I've seen it in lung, but the pleura for sure,
- 20 and peritoneum.
- Q. So if a ferruginous body is forming in
- 22 the peritoneum, presumably the peritoneum had
- 23 asbestos exposure. How did asbestos get into the
- 24 peritoneum, in your opinion?
- 25 A. So -- and these are explanations that

- 1 have been given to me by experts in the field.
 - 2 Because of the shape of the asbestos fiber, it is
 - 3 thought to be able to traverse the diaphragm and
 - 4 reach the peritoneum.
 - 5 Q. What would be the source of exposure?
 - 6 A. Inhalation.
 - 7 Q. So you say someone else essentially told
 - 8 you that. Do you have any opinions yourself, or
 - 9 are you just relying on what those experts told you
 - 10 as to how it got there?
 - 1 A. I don't have any personal experience
 - 12 doing research in the matter.
 - 13 Q. Would you expect asbestos and ovarian
 - 14 tissue to form ferruginous bodies as well?
 - 15 A. Yes.
 - 16 Q. You said that talc found in these
 - 17 plaintiffs' tissues must be contamination. Is that
 - 18 also your opinion about asbestos? If asbestos was
 - 19 found in the gynecologic tissue of these
 - 20 plaintiffs, is it your opinion that that's also
 - 21 contamination?
 - MR. HEGARTY: Objection to form.
 - 23 THE WITNESS: I haven't heard of asbestos
 - 24 being found in these tissues, so I -- I don't know
 - 25 what I would think.

- 1 BY MR. DEARING:
- 2 Q. If inhaled asbestos can reach the
- 3 peritoneum, can it also reach the ovaries?
- 4 MR. HEGARTY: Objection to form.
- 5 THE WITNESS: Theoretically, yes.
- 6 BY MR. DEARING:
- 7 Q. Hospital labs like yours are not
- 8 contaminated with asbestos, are they, as a general
- 9 rule?
- 10 A. There's probably a level of environmental
- 11 asbestos that would be impossible to reduce to
- 12 zero. That being said, it is a very, very, very
- 13 tiny amount.
- 14 Q. Is the amount so small that it's not
- 15 likely to end up on a tissue block?
- MR. HEGARTY: Objection to form.
- 17 BY MR. DEARING:
- 18 Q. Or in a tissue block, I should say.
- 19 A. Unlikely to end up in a tissue block from
- 20 environmental exposure.
- 21 Q. What is your opinion as to what types of
- 22 cancer is caused by asbestos?
- A. There's an increase -- obviously, the
- 24 number one type is mesothelioma, but there is an
- 25 increase in epithelial lung cancer when exposed to

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1 asbestos.

- 2 Q. Are epithelial cells in the lung similar
- 3 morphologically and organically to epithelial cells
- 4 of the ovary?
- 5 A. No, they're extremely different.
- 6 Q. Okay. You've testified that asbestos can
- 7 cause peritoneal carcinomas; right?
- 8 A. Mesothelioma.
- 9 Q. Mesothelioma. And lung mesothelioma.
- 10 Can asbestos cause cancer anywhere else in the
- 11 body, in your opinion?
- 12 A. Not that I've heard of.
- 13 Q. Well, are you aware that IARC has stated
- 14 that asbestos can cause ovarian cancer?
- MR. HEGARTY: Objection to form.
- 16 BY MR. DEARING:
- 17 Q. You know who IARC is?
- 18 A. Yeah, yeah. They are basing that on an
- 19 article that misclassifies ovarian tumors.
- Q. So you're aware they made the statement?
- 21 A. Yeah.
- Q. You just disagree?
- A. I disagree with a lot of things that IARC
- 24 says. I wouldn't be drinking coffee if I believed
- 25 IARC.

1

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- Q. We all take calculated risks.
- 2 Do you know why asbestos is carcinogenic,
- 3 in other words, how it causes cancer?
- 4 A. Yes.
- 5 Q. Can you enlighten me?
- 6 A. Sure. The -- it causes persistent cell
- 7 destruction.
- 8 Q. Okay.
- 9 A. Persistent cell destruction means
- 10 persistent increased cellular reproductive tract,
- 11 which means increase in mutations.
- 12 O. How does it do that?
- 13 A. Physically.
- 14 Q. So the morphology physically damages or
- 15 kills cells?
- 16 A. Correct. It punctures cells.
- 17 Q. Would it have to actually damage the DNA
- 18 of the cell in order to cause the reproductive
- 19 tract problem, or just killing the cell itself is
- 20 encouraging more cells to be created?
- 21 A. Correct, it's killing the cell, causing
- 22 the cells around it to replicate to cover that
- 23 defect. That's what causes it. The asbestos
- 24 itself does not alter DNA.
- Q. Does the asbestos invoke an inflammatory

1 reaction?

- 2 A. Yes.
- 3 Q. Okay. Is that also part of the
- 4 carcinogenesis?
- 5 MR. HEGARTY: Objection to form.
- 6 BY MR. DEARING:
- 7 Q. For example, I imagine one of the cells
- 8 it kills is a macrophage; right?
- 9 A. Yes, it kills many macrophages. But
- 10 the -- but the tissues through which it traverse
- 11 are mainly mesothelial lined, and that's where the
- 12 neoplasia really occurs.
- Q. So are you saying the asbestos fiber is
- 14 mobile, it is moving and killing cells, or that
- 15 cells are attracted to it and --
- 16 A. No, the -- the asbestos fibers are not
- 17 motile, but they move due to their shape.
- 18 Q. And they're just killing cells as they
- 19 go?
- 20 A. I -- that is the accepted theory.
- Q. And is that true of a single asbestos
- 22 fiber?
- 23 MR. HEGARTY: Objection to form.
- 24 BY MR. DEARING:
- Q. In other words, sometimes asbestos fibers

- 1 are found in bundles. Sometimes they're found
- 2 individually. Can you differentiate whether a
- 3 single asbestos fiber can cause the kind of cell
- 4 damage you're talking about?
- 5 A. It can. But again, you're dealing with
- 6 statistics and probabilities, right? So if you
- 7 have one fiber killing X number of cells, what are
- 8 the odds that a mutation will take place versus if
- 9 you have 10,000 asbestos fibers killing cells. And
- 10 I think that's why people who have environmental
- 11 exposure are the ones who are at risk for these
- 12 tumors, whereas people like you and me who
- 13 undoubtedly have asbestos in our bodies, don't.
- 14 Because one -- one fiber just -- the probabilities
- 15 are stacked against it.
- Q. And I'm not suggesting just one fiber in
- 17 the body is all there was. I'm just saying an
- 18 individual fiber. There may be millions of them.
- 19 But an individual fiber as it travels is doing this
- 20 kind of cell damage that you're describing?
- 21 A. Yes.
- Q. Okay. Is there anything about the
- 23 chemical composition of asbestos that's
- 24 carcinogenic, or is it just morphology, or do we
- 25 know?

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- A. As far as I know, it's only the 2 morphology.
- Q. So you mentioned that IARC got it wrong
- 4 because of a misclassification. Can you explain
- 5 what you mean by that?
- A. Yeah. The study that found that asbestos
- 7 caused epithelial ovarian cancer did not -- did
- 8 not -- they got their information mainly from
- 9 cancer registry. So they didn't review those
- 10 tumors. I believe years later they did a
- 11 retrospective analysis of those tumors with
- 12 immunochemistry and found that most of them were
- 13 mesotheliomas.
- 14 Q. Of the ovary?
- 15 A. Yes.

1

- Q. Okay. How do you distinguish a 16
- 17 mesothelioma of the ovary as opposed to an
- 18 epithelial ovarian cancer?
- A. So in some instances you can do it with
- 20 morphology alone, but in some instances you
- 21 actually have to use immunohistochemistry which was 21 is the lining that covers the lung, and go to the
- 22 not available when they published that article.
- Q. Would your typical hospital pathologist
- 24 or community pathologist looking at surgical slides
- 25 immediately be able to differentiate between an
 - Page 127
- 1 ovarian mesothelioma and ovarian carcinoma?
- A. Like I said, in some instances it's quite
- 3 easy. So in the -- in the spindle mesotheliomas, 4 you don't see that kind of morphology in ovarian
- 5 cancer, but in the papillary mesotheliomas they can
- 6 look very similar to serous carcinomas, in which
- 7 case you would do immunohistochemistry.
- Immunohistochemistry today is
- 9 available to pathologists in all hospitals and
- 10 labs. And, gosh, I don't -- I would say probably
- 11 99 percent of ovarian carcinomas have a -- undergo
- 12 an extensive panel of immunohistochemistry.
- Q. So serous carcinoma makes up what,
- 14 probably 80 percent of ovarian cancers that are
- 15 diagnosed?
- 16 A. 70 is the number that I rely on.
- 17 Q. And then a high percentage of that
- 18 70 percent are papillary serous carcinomas; right?
- A. You know, they've stopped classifying
- 20 them as papillary versus nonpapillary.
- Q. Okay. Well, I was just asking because if
- 22 a pathologist -- a surgical pathologist is looking
- 23 at papillary series -- papillary serous carcinoma,
- 24 is it possible that they will misdiagnose that when
- 25 it might really be a papillary mesothelioma in the

1 ovary?

3

- 2 MR. HEGARTY: Object to the form.
 - THE WITNESS: It's very possible, yes.
- 4 BY MR. DEARING:
- 5 Q. Since you're an anatomic pathologist, can
- 6 you walk me through anatomically how inhaled
- 7 asbestos fibers could reach the peritoneum and
- 8 potentially the ovary?
- A. So we know that it reaches -- it
- 10 penetrates and passes through the tissue because it
- 11 has to for inhaled asbestos to reach the pleura.
- 12 Q. Okay.
- 13 A. Most mesotheliomas of the chest occur in
- 14 the parietal pleura, which is the chest wall side
- 15 rather than the lung side. You can get
- 16 mesothelioma starting on the lung side, but most
- 17 are actually parietal pleura. So it has to go into
- 18 the bronchus, to the air sacs of the lung. Once
- 19 it's in the air sacs of the lung, it has to move
- 20 out of the lung through the visceral pleura, which
- 22 parietal pleura, which covers the chest wall. So
- 23 we know it can do that.
- 24 And in industrial exposures sometimes
- 25 very easy to find ferruginous bodies in the
- 1 parietal pleura. Similarly, it can leave the lung,
- 2 traverse the diaphragm, and enter the peritoneal
- 3 cavity.
- 4 Q. So it's not traveling through lymphatic
- 5 space, it's piercing tissue and going through
- 6 tissue itself?
- 7 A. That is the theory, yes.
- 8 Q. Well, could it also travel through
- 9 lymphatic channels?
- 10 MR. HEGARTY: Objection to form.
- 11 THE WITNESS: Yeah, I -- I don't think it
- 12 could because of its shape. It would get stuck a
- 13 lot.
- 14 BY MR. DEARING:
- Q. I know I've bounced around this next 15
- 16 topic a little bit. I'm sorry, I need to put it in
- 17 a more organized way, so I'm just going to ask you
- 18 some questions.
- 19 It's true that you don't consider
- 20 yourself an expert in the field of SEM EDX; right?
- 21 A. Right.
 - Q. And you also don't consider yourself an
- 23 expert in the field of transmission of electron
- 24 microscopy and EDX; correct?
- 25 A. Correct.

- 1 Q. And I think you said also you don't
- 2 consider yourself an expert in Raman spectroscopy?
- A. Correct again.
- Q. And you have no training in any of those 4
- 5 three microscopy techniques?
- A. I have training in transmission
- 7 electromicroscopy as part of diagnosing tumors.
- 8 Haven't used it in decades.
- Q. I've been told it's changed some over the
- 10 decades. It's improved.
- MR. HEGARTY: Objection to form.
- 12 THE WITNESS: TEM -- TEM hasn't changed
- 13 that much. My renal pathologist uses it every day.
- 14 BY MR. DEARING:
- 15 Q. In every report you address
- 16 Dr. Godleski's findings. And to be clear, it's not
- 17 your testimony that he did not identify talc
- 18 properly; right?
- A. Correct. 19
- 20 MR. HEGARTY: Objection to form.
- 21 BY MR. DEARING:
- Q. That was a double negative. You're not
- 23 testifying or opining that he misidentified
- 24 particles as talc; correct?
- 25 MR. HEGARTY: Objection, form.

THE WITNESS: I am not.

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- 1 MR. DEARING: And I e-mailed Susan the
- 2 list, the order.
- 3 MR. HEGARTY: Yeah.
- 4 MR. DEARING: I'm not married --
- 5 MR. HEGARTY: We have it. Yeah, you
- 6 don't have to be married to that order. You can go 7 in whatever order you want.
- 8 MR. DEARING: I was going to say, if you
- 9 wanted a specific order --
- 10 MR. HEGARTY: No, that's fine.
 - MR. DEARING: All right. Let's start
- 12 with Brandi Carl then.
- 13 BY MR. DEARING:
- 14 Q. First of all, does your report contain
- 15 all of your opinions that you intend to offer in
- 16 this case?

11

- A. Unless asked something that would -- that 17
- 18 would prompt my -- an opinion that is -- that I
- 19 haven't thought of, yes, it contains my opinions.
- 20 Q. Are there any other materials that are
- 21 not listed on your reference list that you're
- 22 relying on for your opinions in this matter?
- 23 A. No.

24

- Q. What did Johnson & Johnson lawyers ask
- 25 you to do in this case?

- 1 2 BY MR. DEARING:
- 3 Q. The same would apply to asbestos. If he
- 4 identified asbestos, you're not challenging that
- 5 identification, are you?
- MR. HEGARTY: Objection, form. 6
- 7 THE WITNESS: I would not challenge it.
- 8 BY MR. DEARING:
- Q. The Medical College of Wisconsin and its
- 10 affiliated hospitals and labs, they have scanning
- 11 electron microscopy capability; right?
- 12 A. Yes.
- Q. And I think you just said you also use
- 14 TEM in these facilities; right?
- 15 A. Yes.
- Q. And they have highly skilled, qualified
- 17 microscopists to operate them?
- 18 A. Yes.
- 19 Q. And you didn't consult with any other
- 20 microscopists or pathologists about any of the
- 21 tissue that you reviewed in these cases; right?
- 22 A. I have not.
- Q. Okay. Let's start looking at some
- 24 specific reports. If we can, let's start with
- 25 Brandi Carl.

- Page 133 A. They asked me to look at the pathology of
- 2 Ms. Carl's tumor and see if there was any evidence
- 3 that there was talc present in her tissues that
- 4 could have influenced the genesis of this tumor.
- 5 Q. In your opinion, did Ms. Carl's
- 6 cancer -- strike that.
- 7 In your opinion, was Mrs. Carl's
- 8 cancer properly diagnosed by her treating
- 9 pathologist?
- 10 A. Yes.
- 11 Q. Do you disagree with any of the
- 12 statements or opinions of Ms. Carl's treating
- 13 pathologist?
- 14 MR. HEGARTY: Objection.
- 15 BY MR. DEARING:
- Q. Incidentally, I have all the pathology 16
- 17 reports with me if you need to look at any of them.
- 18 A. Yes, I did not believe that
- 19 Ms. Carl's -- Ms. Carl had invasive implants. I
- 20 thought her implants were noninvasive.
- 21 Q. What's the basis of your opinion?
- 22 A. The morphology of the implants.
- Q. That's something you actually observed on 23
- 24 the slides?
- 25 A. Yes.

- 1 Q. Is there anything else -- any other
- 2 pathology opinions that you disagree with?
- 3 A. Yes. I disagreed with microinvasion. I
- 4 thought it was just a serous borderline.
- 5 Q. Okay. Incidentally, what's the
- 6 difference between micropapillary serous borderline
- 7 and papillary serous?
- 8 A. There's an important distinction.
- 9 Micropapillary refers to a very specific
- 10 morphologic trait where instead of the tumor having
- 11 hierarchal branching, meaning thicker papillae
- 12 leading to thinner papillae, the micropapillary
- 13 borderlines contain mainly the same size papillae.
- 14 And these papillae, instead of having just a single
- 15 or a few layers of cells, contain very, very tall
- 16 accumulations of epithelium.
- 17 This morphologic appearance correlates
- 18 with invasive implants in the peritoneum. It's not
- 19 necessary sequela of the micropapillary, but more
- 20 the percentage of micropapillary tumors with
- 21 invasive implants is much, much higher than that of
- 22 a serous borderline papillary tumor.
- Q. It's your opinion that she had a serous
- 24 borderline tumor that was not invasive; is that
- 25 right?

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- 1 A. Correct.
- Q. Is there any clinical significance to
- 3 that distinction with regard to treatment or
- 4 outcomes?
- 5 A. Yes. Microinvasive borderlines have the
- 6 same prognosis as borderline tumors. They would
- 7 not be -- should not be treated differently.
- 8 Invasive implants, on the other hand, change the
- 9 therapy for the patient.
- 10 Q. So invasive borderline tumors, do they
- 11 require more aggressive treatment?
- 12 A. So you -- you said invasive. I used the
- 13 term microinvasive, which is what the pathologist
- 14 called it.
- 15 Q. Okay.
- 16 A. Microinvasive borderlines do not require
- 17 additional therapy.
- 18 Q. Okay. So is there any clinical
- 19 distinction between serous borderline and
- 20 microinvasive serous borderline?
- A. There is a distinction in that the
- 22 microinvasive is actually invading. But that
- 23 invasion, if it's smaller than, I think it's two
- 24 millimeters, does not alter the prognosis of the
- 25 patient, therefore does not require therapy.

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- Q. Okay. So the purpose of you making that
- 2 distinction is just you observed it differently, is
- 3 that all?

8

- 4 A. Correct.
- 5 Q. Okay. Are you saying that it -- well,
- 6 let me just ask you. Do you think that she
- 7 received proper care and treatment?
 - A. So she received Taxol copper
- 9 platinum, likely because of the invasive implants.
- 10 She -- you can offer an advanced stage serous
- 11 borderline tumor without invasive implants
- 12 chemotherapy, but some people would actually
- 13 observe instead of treat. But she received
- 14 accepted treatment for her tumor.
- 15 Q. Very delicately stated.
- 16 A. I would not be able to say that was
- 17 wrong.
- 18 Q. I understand.
- 19 A. It's not. Because some oncologists will
- 20 treat. Some oncologists will observe.
- Q. So the only practical distinction between
- 22 your diagnosis and the treating pathologist's is if
- 23 it is invasive, then Taxol copper platinum may be
- 24 the proper course. If it's not invasive, then it
- 25 may be something you just remove and observe?
- Page 137
- rage 133
 - 2 not the tumor itself, but the implants.3 O. Okay.
 - Q. Okay.A. Okay. If a pathologist -- if I diagnose
 - 5 somebody with invasive implants, I would say that

A. Or give chemo to. So we're talking about

- 6 95 to 99 percent of oncologists would give
- 7 chemotherapy. If I diagnose somebody with
- 8 noninvasive implants, I would say maybe half of the
- 9 oncologists would watch.
- 10 Q. Okay.
- 11 A. So -- but again, both are accepted ways
- 12 of managing your patient.
- 13 Q. Is there anything else -- any other
- 14 pathological opinions that you disagree with?
- 15 A. No.
- 16 Q. What is your understanding of Ms. Carl's
- 17 usage of Johnson's baby powder or talcum powder
- 18 products, or do you know?
- 19 A. I don't remember.
- 20 Q. Do you think that's information you had
- 21 at one time, or is that not relevant to your
- 22 opinions?
- A. It's not relevant to my opinion.
- Q. Did you make any new slides from
- 25 Ms. Carl's tissue, or did you review surgical

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- 1 slides that already existed?
- A. I reviewed surgical slides that already sexisted.
- 4 Q. And did you study the tissue blocks that
- 5 were made in her case?
- 6 A. I did not.
- 7 Q. Did the lawyers even send you the tissue
- 8 blocks in this case?
- 9 A. No.
- 10 Q. Did you request to see them?
- 11 A. No.
- 12 Q. I guess, let me just ask you across the
- 13 board. Did they send you tissue blocks in any of 13
- 14 these cases, any of these seven? And if you
- 15 prefer, I'll ask you for each one, but --
- 16 A. No, no, no. I'm just trying to think. I
- 17 did not receive tissue blocks on any of these
- 18 cases.
- 19 Q. Okay. Did you request tissue blocks?
- A. I did not.
- Q. Is that because you didn't think you
- 22 would find anything useful in the tissue blocks?
- A. Correct. I'm a firm believer that the
- 24 representative section adequately allows me to
- 25 diagnose the conditions that the patient has.
 - Page 139
- 1 Q. You would agree with me, wouldn't you,
- 2 that Dr. Godleski provided to the Johnson & Johnson
- 3 lawyers, and presumably to you, the precise
- 4 locations of particles that he identified in tissue
- 5 blocks; right?
- 6 MR. HEGARTY: Objection to form.
- 7 BY MR. DEARING:
- 8 Q. And told you what blocks they came from,
- 9 obviously?
- 10 A. Yes, he provided the blocks where it came
- 11 from.
- 12 Q. And also in the data that he provided
- 13 showed the exact coordinates of where those
- 14 particles were located, right, by SEM?
- 15 A. I was actually unaware of that.
- 16 Q. Okay. Well, assuming that he provided
- 17 the coordinates and the blocks, isn't it true that
- 18 you could have asked colleagues in the SEM
- 19 department here to look at the same blocks and look
- 20 at the exact same particles that Dr. Godleski
- 21 looked at?
- A. But I wouldn't need to do that.
- 23 Q. Right. I know you felt like you didn't
- 24 need to, but you could have done that, couldn't
- 25 you, if you wanted to?

- 1 A. For what purpose?
 - 2 Q. Whatever purpose you wanted. I'm just
 - 3 asking if it could be done.
 - A. It could be done, yeah, sure.
 - Q. Okay. Looking specifically at your
 - 6 report -- let me just ask you. Can you estimate
 - 7 about how many different cases you've reviewed for
 - 8 Johnson & Johnson -- or for the lawyers for Johnson
 - 9 & Johnson over the past --
 - 10 A. Twelve years.
 - 11 Q. -- twelve years since you got involved in
 - 12 this litigation?
 - A. I would say in the neighborhood of 30.
 - Q. I can identify probably 15 off the top of
 - 15 my head that actually went to trial or -- actually,
 - 16 more than that. Well, 30 is your number, you
 - 17 think?

14

- 18 A. About, yeah. I mean, it's an estimate.
- 19 Q. You state in here in the first paragraph
- 20 of your report, and first paragraph of every
- 21 report, one of the things that you looked at is
- 22 whether there's histologic evidence supporting
- 23 internal exposure to talc-based body powder. And
- 24 then later on you say there is not.
- 25 Isn't it true that you have never once

- 1 said that there is histologic evidence supporting
- 2 internal exposure to talcum-based baby powder in
- 3 any of the cases that you've looked at for the
- 4 lawyers for Johnson & Johnson?
- 5 A. There's no evidence for it being talc;
- 6 correct. There are, I believe, two cases in this
- 7 group where I see particles and macrophages in
- 8 lymph nodes.
- 9 Q. What is the mean age of women with serous
- 10 borderline tumors? I know the mean age for serous
- 11 carcinomas, for high-grade serous, is 65 or so, but
- 12 I didn't see -- and maybe there isn't one.
- 13 A. It's two decades earlier in life. So
- 14 it's in the fifth decade of life.
- 15 Q. So women in their 50s typically?
- 16 A. Women in their 40s.
- 17 O. In their 40s.
- 18 A. Yeah.
- 19 Q. There seems to be about a 20-year
- 20 disparity between high-grade serous carcinoma, the
- 21 mean age of women at 65, and low-grade serous
- 22 carcinoma, age 43. What's the explanation for the
- 23 disparity?
- A. They're two different, entirely
- 25 different, tumor processes. And I don't know -- I

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- 1 don't think anybody knows why the high-grade serous
- 2 carcinoma doesn't happen earlier. But certainly
- 3 neoplasms are different enough to not be
- 4 surprising -- for it not to be surprising that they
- 5 differ in many aspects.
- Q. What is it about low-grade serous
- 7 carcinomas that cause them to be found in much
- 8 younger women.
- A. That they occur sooner.
- 10 Q. Well, I know. But why are they occurring
- 11 sooner than high-grade serous?
- A. It likely has to do with the mutations
- 13 that they develop that -- that manifest themselves
- 14 earlier in life.
- 15 Q. In your high-grade serous carcinoma
- 16 paragraph, you don't mention STIC lesions. Is it
- 17 your opinion that most serous carcinomas began in
- 18 the fallopian tube, or is that an outdated theory?
- MR. HEGARTY: Objection to form.
- 20 BY MR. DEARING:
- 21 Q. Or you just disagree with it?
- 22 A. I am in the camp that believes that most
- 23 ovarian carcinomas occur -- start in the ovary from
- 24 fallopian tube epithelium.
- 25 Q. Okay. That's different than a STIC

- A. Yeah.
- Q. Then you say -- well, in that first
- 3 sentence you said, "Like most cancers, ovarian
- 4 cancers develop as a result of genetic mutations
- 5 whether inherited or acquired." By acquired, are
- 6 you referring to sporadic mutations?
- 7 A. Yes.
- Q. You're not including environmental
- 9 exposure in acquired mutations; is that right?
- 10 A. I am not.
- 11 Q. You discuss later on on that page
- 12 Ms. Carl's family history. And you state that
- 13 Ms. Carl's family history includes a maternal
- 14 grandmother with lung and/or pancreatic cancer, and
- 15 a maternal grandfather with stomach or esophageal
- 16 cancer. You would agree with me that neither of
- 17 those cancers likely contributed to Ms. Carl's
- 18 ovarian cancer; correct?
- 19 A. I do agree with you.
- 20 Q. To state it another way, neither of those
- 21 cancers of her relatives increase her risk of
- 22 getting ovarian cancer; correct?
- 23 A. Correct.
 - Q. You state her medical history is
- 25 significant for nulliparity, infertility, pelvic

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24

- 1 lesion; right? A. It is different than a STIC lesion.
- 3 Q. It's S-T-I-C.

2

- 4 In your opinion, what is the
- 5 carcinogenesis of serous borderline tumors? In
- 6 other words, how are they formed?
- 7 A. They form after serous cells within the
- 8 ovary undergo several types of mutations, and those
- 9 would be BRAF and KRAS mutations.
- 10 Q. Any idea what causes those mutations?
- A. Likely just mismatch repair gene
- 12 deficiencies.
- Q. You say in the second paragraph on
- 14 page 4, "Like most cancers, ovarian cancers develop
- 15 as a result of genetic mutations, whether inherited
- 16 or acquired. To date, old age, family history of 17 ovarian or breast cancer, and inherited mutations
- 18 in known cancer susceptibility genes, are the
- 19 strongest risk factors associated with the
- 20 development of ovarian cancer."
- When you say family history of ovarian
- 22 and breast cancer, you're referring to first-degree
- 23 relatives; correct?
- 24 A. First and second.
- 25 Q. Oh, you're including second-degree?

- 1 endometriosis and obesity. Would you agree with me
- 2 that none of those medical findings likely
- 3 contributed to her serous borderline tumor?
- A. I don't agree with you. So parity
- 5 influences ovarian cancer.
- Q. Okay. So the fact that she had no
- 7 children put her at a higher risk of this
- 8 borderline tumor.
- 9 A. At a slightly higher risk, yes.
- 10 Q. And do you know what that relative higher
- 11 risk is?
- 12 A. Not off the top of my head.
- Q. Would you agree that infertility, pelvic
- 14 endometriosis, and obesity, did not likely
- 15 contribute to her ovarian cancer?
- 16 A. Yes, I agree.
- 17 Q. The next sentence says, "Genetic
- 18 counseling and testing to determine potential
- 19 hereditary factors contributing to Ms. Carl's
- 20 development of serous borderline tumor was
- 21 recommended but not done." I couldn't find where
- 22 that was recommended. Do you know who recommended
- 23 that she get genetic testing?
- 24 A. One of her treating physicians.
- 25 Q. Because my understanding was her treating

5 44	5 440
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1 physician said because it was a borderline tumor,	1 demonstrably in the plane of or associated with
2 he wasn't going to recommend testing.	2 tissue, and uniformly lack the expected tissue
3 MR. HEGARTY: Objection to form.	3 reaction that would corroborate a true foreign body
4 THE WITNESS: Yeah, it was one of her	4 exposure."
5 treating clinicians.	5 You say, "As expected such particles
6 BY MR. DEARING:	6 are rarely encountered in some of Ms. Carl's
7 Q. You don't remember which one?	7 pathology slides." For some reason that statement
8 A. I don't.	8 doesn't make sense to me. Can you explain that?
9 Q. Okay. I couldn't tell from those cites	9 Are you saying it is rarely encountered?
10 which one. Anyway. As you sit here now, you don'	10 A. That means that there's not a lot of
11 know who made that recommendation?	11 them.
12 A. I don't remember, no.	12 Q. Okay. Well, if talc is ubiquitous in the
Q. The next section is your examination of	13 tissue processing I'm sorry. If talc is
14 the pathology slides section. And you state that,	14 ubiquitous in the labs and in tissue processing,
15 "My review of the slides reveals that Ms. Carl's	15 wouldn't you expect to see talc on every
16 tumor is a serous borderline tumor with	16 histological slide?
17 micropapillary features and noninvasive	17 A. You pretty much see them on most
18 desmoplastic and nondesmoplastic implants."	18 histological slides when you look for them.
19 I have to admit, I have not seen that	19 Q. So that's not really rarely encountered.
· ·	
20 term before. What is desmoplastic and	20 That's frequently encountered; right?
21 nondesmoplastic?	A. Well, it's rarely encountered on a single
A. So desmoplasia is the reaction of the	22 slide.
23 tissue around the implant. And it is a fibrous	Q. Meaning?
24 reaction. A lot of extracellular collagen. The	24 A. There's not a lot of particles per
25 importance of that is that invasion I'm	25 slides.
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1 sorry desmoplasia is something that occurs when	1 Q. Okay. Meaning only a few particles per
_	
1 sorry desmoplasia is something that occurs when	1 Q. Okay. Meaning only a few particles per
1 sorry desmoplasia is something that occurs when 2 some tumors invade.	1 Q. Okay. Meaning only a few particles per 2 slide?
 sorry desmoplasia is something that occurs when some tumors invade. Q. Okay. A. Which is likely what made the treating 	 Q. Okay. Meaning only a few particles per slide? A. Correct. Q. But you would likely find them on almost
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THE WITNESS: There are differences

25

25 are not confirmed to be talc and are not

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1 between the two.

- 2 BY MR. DEARING:
- Q. One of those differences would be the
- 4 size of the talc particles; right?
- 5 A. Yes, the mean size of pharmaceutical
- 6 grade talc is larger than the mean size of cosmetic
- 7 talc, but there's overlap.
- 8 Q. Exactly. And the reason you want to use
- 9 larger talc particles in talc pleurodesis is you're
- 10 trying to invoke that inflammatory reaction that
- 11 includes the granulomas and the giant cells, right,
- 12 to fill the pleural space. So the larger the talc,
- 13 the more of the inflammatory -- or the greater the
- 14 inflammatory response; correct?
- MR. HEGARTY: Objection to form.
- 16 THE WITNESS: I'm not certain that that
- 17 is correct, because cosmetic talc does elicit a
- 18 foreign body reaction, including granulomatous
- 19 inflammation.
- 20 BY MR. DEARING:
- Q. But you know cosmetic talc also elicits a
- 22 lesser inflammatory reaction like a macrophage
- 23 reaction; right?
- MR. HEGARTY: Objection to form.
- THE WITNESS: Yes. So the cosmetic talc

- 1 injected into the space?
 - 2 A. Yes, it would. Obviously there's enough
 - 3 talc to obliterate the entire pleural space, so
 - 4 it's -- if there -- if you just put in a couple of
 - 5 droplets, it wouldn't obliterate the space.
 - Q. And my point of asking is once the space
 - 7 is obliterated, the inflammation curtails; right?
 - 8 A. No, the inflammation remains static, and
 - 9 it remains static for pretty much the lifetime of 10 the patient.
 - 1 Q. And most of those patients that get the
 - 12 pleurodesis procedure are already in end stage of
 - 13 disease; right?
 - 14 MR. HEGARTY: Objection to form.
 - 15 THE WITNESS: That's -- that is -- I
 - 16 don't have the statistics, but a very common reason
 - 17 to perform pleurodesis are pulmonary blebs from
 - 18 patients with emphysema. And those patients are
 - 19 not end stage at all. And there's publications
 - 20 with follow-up of over 20 years on some of these
 - 21 patients.

1

- 22 BY MR. DEARING:
- Q. Well, some of them aren't. But would you
- 24 agree most of the patients that undergo pleurodesis
- 25 are end stage disease?

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- 1 ranges in size from slightly over a micron to up to
- 2 30 microns. Anything under five will more likely
- 3 be phagocytized by a macrophage. Anything over
- 4 five will form a granulomatous reaction.
- 5 BY MR. DEARING:
- 6 Q. Okay. Of course presumably, medical
- 7 grade talc or pharmaceutical grade talc doesn't
- 8 contain asbestos; right?
- 9 MR. HEGARTY: Objection to form.
- 10 THE WITNESS: Does not contain
- 11 significant amount of asbestos; correct.
- 12 BY MR. DEARING:
- 13 Q. And would you describe the inflammatory
- 14 reaction in the pleurodesis procedure as an acute
- 15 reaction as opposed to a chronic reaction or acute
- 16 inflammation versus chronic inflammation?
- 17 A. No, it does not cause acute inflammation.
- 18 Q. Okay. How would you describe the

19 inflammation it causes?

- 20 A. It causes foreign body granulomatous
- 21 reaction.
- Q. Is it an ongoing reaction, or once the
- 23 pleural spaces are filled -- well, let me ask you.
- 24 Does the degree of reaction depend on the amount of
- 25 talc injected into the -- or the talc slurry

- MR. HEGARTY: Objection to form.
- 2 THE WITNESS: I don't know the answer
- 3 to that question. I don't know how many are
- 4 for -- for malignant infusions versus how many are
- 5 for pulmonary blebs.
- 6 BY MR. DEARING:
- 7 Q. Since your specialty is gynecologic
- 8 pathology, do you have a lot of personal experience
- 9 with pleurodesis in pulmonary pathology?
- 10 A. I've ran -- I've run into, it's either
- 11 three or four cases in which I performed an autopsy
- 12 on a patient who had undergone pleurodesis.
- 3 Q. And that -- that experience with those
- 14 three or four patients, is that what you're relying
- 15 on for your opinions about the -- whether the
- 16 inflammatory reaction is acute or chronic or -- or
- 17 granulomatous?
- 18 MR. HEGARTY: Objection to form.
- 19 THE WITNESS: So I rely on the literature
- 20 as well. The literature -- nowhere in the
- 21 literature does it state that you get acute
- 22 inflammation when you -- when you expose body
- 23 tissues to talc. And the literature does state
- 24 that when granulomas are seen many years after the
- 25 formation of -- of the granulomatous reaction

Page 154 Page 156 1 which --1 A. No. 2 BY MR. DEARING: 2 Q. That's why I was asking. 3 Q. But I'm referring to pleurodesis right 4 4 now. Q. I'm sorry that wasn't very clear. So 5 5 this hypothetical of perineal itching as a A. Yes. Q. Okay. 6 precursor that leads to ovarian cancer, that's not 6 7 7 anything you've actually experienced in your A. So both the literature and my experience 8 is that the granulomas are long term. 8 clinical practice; right? 9 A. Correct. It's a hypothetical. Q. Isn't it true that most patients who 10 undergo talc pleurodesis already have some type of 10 Q. At the top of page 7, you mention 11 cancer? 11 Dr. Wolf and her opinions. 12 MR. HEGARTY: Objection, asked and 12 A. Yes. 13 answered. 13 Q. And you state, "When evaluating cohort 14 BY MR. DEARING: 14 studies, there is no association between talc use 15 Q. No, I said end stage disease before. 15 and the development of ovarian cancer." And you 16 This is a little different. 16 cite O'Brien 2020. 17 17 A. So I -- anybody who has a malignant Would your opinions about talc and 18 infusion is close -- very close to being end stage. 18 ovarian cancer be different if there was a cohort But to answer that question, again, I 19 study that showed an association between talc use 20 don't know the percentage of cases that undergo 20 and development of ovarian cancer? 21 A. No. 21 talc pleurodesis who are malignant. It could be 22 more than 50 percent. It could be less than 22 MR. HEGARTY: Objection to form. Calls 23 50 percent. I just don't know. 23 for speculation. 24 Q. Okay. Incidentally, while we're talking 24 BY MR. DEARING: 25 about particle sizes, surgical gloves were dusted 25 Q. So your opinions about talc and ovarian Page 155 Page 157 1 with industrial grade talc; right? 1 cancer are independent of the epidemiology studies; 2 A. I don't know. 2 right? 3 MR. HEGARTY: Objection. 3 MR. HEGARTY: Objection to form. 4 THE WITNESS: I don't know the answer to 4 THE WITNESS: Correct. 5 that question. 5 BY MR. DEARING: 6 BY MR. DEARING: Q. Further down in that paragraph you state, Q. Okay. At the bottom of page 6 of this 7 "The absence of foreign body responses to tens of 8 report you state that the talc use and ovarian 8 thousands of ovaries examined by me and numerous 9 cancer might be coincidental. And you say, for 9 other gynecologic pathologist colleagues, despite 10 example, if the precursor lesions of ovarian cancer 10 the common use of perineal talc, is evidence that 11 caused perineal itching, women might use talc in an 11 perineal talc does not reach the ovaries in any 12 attempt to soothe the discomfort. 12 clinically significant quantity." What do you mean 13 by "clinically significant quantity"? 13 What precursor lesions to ovarian 14 cancer might cause itching? What are you talking 14 A. A quantity that would cause a reaction of 15 about? 15 the body to it. A. The earlier forms of -- of cell change 16 Q. Okay. So you don't seem to be saying 17 that don't acquire the final mutation that causes 17 that perineal talc application cannot reach the 18 it to be cancer. 18 ovaries at all. You're saying it cannot reach the 19 Q. That causes itching sometimes? 19 ovaries in any clinically significant quantity; 20 A. It is clearly speculative here. 20 right? 21 21 Q. Okay. MR. HEGARTY: Objection, form. 22 A. I'm just saying as an example, a 22 BY MR. DEARING: 23 23 hypothetical. Q. In other words, are you saying some Q. I didn't know if that was something that 24 particles might get there?

A. Anything is possible. If it -- if any

25

25 you encountered in your practice.

1 particle of talc gets there, it doesn't do

- 2 anything.
- Q. Okay. You state in the next paragraph,
- 4 where you are discussing Dr. Godleski's findings,
- 5 you state, in the next to the last sentence in that
- 6 paragraph that it's important to note that the
- 7 particle, which is at least 350 microns in its
- 8 largest dimension, is not contained within a
- 9 macrophage. Is that a typo, or did you mean to say
- 10 350 microns?
- A. No, that's not a typo.
- Q. Okay. Well, you wouldn't expect to find 12
- 13 a 350 micron particle in a macrophage, would you?
- A. You would not. But then I go on in that
- 15 sentence to say that -- or otherwise associated
- 16 with a foreign body reaction.
- 17 Q. You've stated in this report and in
- 18 previous testimony that talc found by
- 19 Dr. Godleski is most likely contamination that
- 20 occurs during the tissue process -- tissue
- 21 paraffination -- paraf -- am I saying that right?
- 22 A. Just say processing.
- 23 Q. When tissue is being processed. That was
- 24 a horrible -- I'm going to start that over.
- 25 You've stated in your report, you've

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- 1 with your reports is your litigation history over
- 2 the preceding four years. And would you say that
- 3 those four years would be consistent with the
- 4 average of years that you've testified over the
- 5 past 20 years?
- A. It's changed somewhat.
- 7 Q. How about just in the past twelve years,
- 8 are you -- is your annual litigation work about the
- 9 same?
- 10 A. Very similar, yes.
- 11 Q. With an exception for the COVID year
- 12 but -- okay.
- 13 (Exhibit 4 marked for identification.)
- 14 BY MR. DEARING:
- 15 Q. I'm showing you what I'm marking as
- 16 Exhibit Number 4, which are the invoices that I
- 17 received pertaining to Ms. Carl's case.
- And do these accurately reflect the
- 19 amount of time and income you have received from
- 20 your work on the Carl case as best as you and your
- 21 wife can recall?
- 22 A. Yes, up to February of 2024.
- 23 Q. Okay. Does any of the income you earned
- 24 in this litigation go to the Medical College of
- 25 Wisconsin?

- 1 testified that the talc found by Dr. Godleski is
- 2 most likely to be the product of lab contamination
- 3 that occurred during tissue processing.
- 4 Part of that process is the tissue
- 5 being dehydrated and then paraffinized. How does
- 6 talc infiltrate that process? In other words,
- 7 where does the talc contamination occur during that
- 8 process that would result in talc actually being in
- 9 the corpus of the tissue?
- 10 A. Sure. So when -- when the tissue is
- 11 dehydrated with serial dilutions of alcohol, and
- 12 then the alcohol is removed by using an organic
- 13 solvent, xylene, the membranes of the cells become
- 14 permeable and allow the passage of paraffin. We
- 15 know that paraffin is contaminated with particles.
- 16 Commercial paraffin contains numerous particles,
- 17 including talc.
- 18 Q. Is that published somewhere? I mean, how
- 19 do you know that?
- 20 A. It's in the product inserts.
- 21
- 22 A. So when the tissue goes from xylene to
- 23 xylene plus paraffin, you basically can permeate
- 24 the entire thing with particles.
- 25 Q. Okay. One of the things you provided

- 1 A. No.
- 2 Q. Does it go to anyone other than you?
- 3 A. Well, I have a corporation.
- 4 Q. Okay.
- 5 A. And it would -- with which I pay
- 6 employees.
- 7 Q. Okay. I'm not aware of that. Can you
- 8 tell me about that? What's the name of your
- 9 corporation?
- 10 A. It's called Women's Pathology Services,
- 11 LLC.
- 12 Q. What is the business of that corporation?
- A. It is -- it handles all of my medicolegal
- 14 work as well as pharmaceutical trials. I think
- 15 that's basically it.
- Q. So the income derived from litigation
- 17 goes -- is paid to the corporation. And then does
- 18 the corporation pay you a salary, or how does that
- 19 work?
- 20 A. Correct, yes, it does. I take it as
- 21 income.
- Q. Okay. Is your wife an employee of the 22
- 23 corporation?
- 24 A. Yes.
- 25 Q. Do you have other employees?

- A. My daughters work -- work for me 1
- 2 sometimes.
- Q. Are they pathologists? 3
- 4 A. No.

10 seven cases?

- 5 Q. What kind of work do they do for you?
- A. They -- they will sometimes summarize
- 7 records for me. One of my daughters is a nurse.
- 8 She's very adept at going through medical records.
- Q. Did your daughters do any work in these
- 11 A. I don't think so. Most of the work that
- 12 they do is on birth injury.
- 13 Q. How much do you think Johnson & Johnson
- 14 or their lawyers have paid you for your litigation
- 15 work since you started twelve or so years ago?
- A. It's possibly in the neighborhood of
- 17 getting close to a million dollars.
- Q. And any idea about how much of
- 19 outstanding work exists that you haven't been paid
- 20 for? In other words, about how much do they owe
- 21 you now that you haven't invoiced for?
- 22 A. Oh, I have no idea. Yeah, I --
- Q. I assume you plan to invoice them for the
- 24 work in these seven cases that you haven't billed
- 25 them for yet?

- Page 163
- 1 A. Yes, I do plan on doing that.
- MR. DEARING: Mark, I would just request 2
- 3 that we get provided with those invoices should
- 4 they ever be made.
- 5 MR. HEGARTY: We will provide those
- 6 invoices.
- 7 THE WITNESS: While you look, I'm going
- 8 to take a couple minutes' break to run to the
- 9 restroom.
- 10 MR. HEGARTY: Let's go off the record.
- (Break taken.) 11
- 12 BY MR. DEARING:
- Q. So the last question I wanted to ask you
- 14 about Carl is whether you have copies of any chain
- 15 of custody documents related to the slides. I
- 16 don't, or I'd show them to you. I don't know that
- 17 any exist. I'm just asking.
- 18 A. I'm pretty sure they do exist.
- 19 Q. Okay.
- 20 A. I don't have them with me.
- Q. That was one of the things we asked to be
- 22 produced in the notice of deposition, so I would
- 23 ask that they get produced if they -- if you have
- 24 them. I don't have any.
- 25 MR. HEGARTY: You're talking about any

8

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- 1 chain of custody documents, copies of which that
- 2 Dr. Felix still has?
- 3 MR. DEARING: Yes, if he made copies of
- 4 any them, or if you guys have them. I don't know
- 5 if there is one even. But if there is one, I'd
- 6 like to see a copy of it. I don't know who's
- 7 actually maintaining it.
 - MR. HEGARTY: We'll follow up on that.
- MR. DEARING: Okay. I know sometimes we
- 10 don't have chain of custody forms. And maybe we
- 11 don't in this one, 'cause it was a long time ago.
- 12 BY MR. DEARING:
- Q. In the -- in your CV, at the end of your
- 14 CV -- I mentioned I was going to ask you about the
- 15 case control study of ovarian cancer that you
- 16 worked on. It shows the dates of 1993. It's in
- 17 your grants section.
- 18 A. My what?
- 19 Q. Research grants that you received. You
- 20 identify a case control study of ovarian cancer.
- 21 My pages to your CV aren't numbered, but it's sort
- 22 of right in the middle. Anyway, you received \$1.5
- 23 million, looks like, from the NCI. Do you see what
- 24 I'm referring to?
- 25 A. Yeah, I was just co-investigator on that.

- 1 I did not receive a million and a half.
- 2 Q. So what was that case control study
- 3 about? That's really my question.
- A. I believe it was about borderline tumors.
- 5 Jesus, it was so long ago.
- Q. Do you know if it was ever published, any
- 7 results were ever published?
- A. I'm sure there were some results
- 9 published. My role was in -- basically doing
- 10 a -- if memory serves me, is doing a validation of
- 11 diagnoses on a -- I believe ten percent of the
- 12 cases they were able to retrieve.
- 13 Q. Okay.
- 14 A. Just to confirm the histology.
- 15 Q. Moving to the next case, Diana
- 16 Balderrama. First let me ask you: Does your
- 17 report contain all of your opinions that you intend
- 18 to offer in this case?
- 19 A. Yes.
- 20 Q. Are there any materials not listed on
- 21 your reference list that you're relying on for your
- 22 opinions in this case?
- 23 A. No.
- 24 Q. And in your opinion, was Ms. Balderrama's
- 25 cancer properly diagnosed by her treating

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1 4 01-

- 1 pathologist?
- A. Kind of.
- 3 Q. Can you explain that?
- 4 A. So the treating pathologist diagnosed her
- 5 endometrial cancer, and the treating pathologist
- 6 diagnosed her ovarian cancer, and then was
- 7 noncommittal as to whether it was a single tumor
- 8 versus synchronous primaries. And so it is my
- 9 opinion that that is highly likely that this is a
- 10 metastatic endometrial cancer for a variety of
- 11 reasons.
- 12 Q. When you say the pathologist was
- 13 noncommittal, they did ultimately opine that these
- 14 were synchronous tumors; right?
- 15 A. I -- let me find the report. Yeah, I
- 16 don't think that the pathologist -- I don't think
- 17 she definitively diagnosed it as synchronous. She
- 18 said the lack of ovarian endometriosis would favor
- 19 secondary involvement from an endometrial tumor,
- 20 while the overall size of the ovarian neoplasm and
- 21 unilateral involvement of the ovary would suggest a
- 22 primary independent ovarian neoplasm. So she's
- 23 noncommittal.
- Q. In the microscopic description section of
- 25 the pathology report, she goes through section A

- A. Okay.
- Q. And you can see where she's writing in
- 3 the section B of the microscopic description and
- 4 diagnosis, she makes reference to synchronous
- 5 neoplasm. So isn't she committing, by doing that,
- 6 to say that these are most likely synchronous
- 7 tumors?
 - A. I mean, in one part of her report she
- 9 says she can't be sure, and --
- 10 Q. Right. Do you recall seeing in other
- 11 parts of the medical records where the treating
- 12 surgeon opined that these were synchronous tumors?
- A. I do recall reading that, several people
- 14 who referred to it as synchronous, yes.
- 15 Q. So is it your opinion that they
- 16 just -- they got it wrong?
- 17 A. Yes. It is not -- if you read the latest
- 18 treaties on this, there is -- there is no certainty
- 19 as to the -- as to the classification of
- 20 synchronous versus metastatic. There are criteria
- 21 that, when fulfilled, lead you to say one versus
- 22 the other. The criteria include to have it
- 23 synchronous, it must be less than half mononucleal
- 24 invasion.
- 25 Q. Isn't this right on that?

- 1 and describes the right fallopian tube and ovary
- 2 with an endometrioid adenocarcinoma. And then she
- 3 in section B, describing the uterus and
- 4 endometrium, she refers to an endometrioid
- 5 adenocarcinoma. And below that she writes
- 6 synchronous neoplasm, and she describes the acidic
- 7 fluid and other things.
- 8 A. I'm sorry, what page is that?
- 9 Q. Well, the same page you were just reading
- 10 from. Hold on. And then at the bottom -- so this
- 11 is where you were just reading from. If you go
- 12 down to the bottom, there's A and B. And the next
- 13 page is where B continues.
- 14 A. My report is formatted differently than
- 15 yours.
- 16 Q. Okay.
- 17 A. May I see?
- 18 Q. Sure. Let me mark this one as an
- 19 exhibit, and I'll give you this one.
- 20 (Exhibit 5 marked for identification.)
- 21 BY MR. DEARING:
- Q. So I'm marking as Exhibit 5 the
- 23 Providence Holy Cross Medical Center pathology
- 24 report, which has a Bates stamp on it of
- 25 DBalderramaPL-PHCMC-000183.

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 A. Dr. Sampson diagnoses it as outer half
- 2 greater than 50 percent. Then she -- the other
- 3 criteria is that it's not -- it's stage -- it can't
- 4 be disseminated or have involvement of other
- 5 organs. Her cervix is involved, so that would make
- 6 her a stage two endometrial cancer. And because of
- 7 those two reasons, I would classify it as a
- 8 metastatic endometrial cancer of the ovary.
- 9 Q. Isn't the degree of invasion sort of
- 10 right on the dividing line? In other words --
- 11 A. It's greater than 50 percent. So these
- 12 are not -- these are not optional criteria. These
- 13 are -- FIGO defines it as 50.0001 percent invasion
- 14 is outer half.
- 15 Q. Okay.
- 16 A. Okay? So it's -- it's sort of like a
- 17 501, two, or three. You can't say 501 to two.
- 18 Q. Is it fair to say that the hospital
- 19 pathologist interpreted the degree of invasion
- 20 different than you did?
- 21 A. No, her degree of invasion is 1.2 out of
- 22 2.2, greater than 50 percent. That would be on the
- 23 same place where she calls it synchronous.
- Q. Okay. Let me ask you about endometrial carcinomas. Type one, the distinction between

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- 1 endometrial carcinomas between type one and type
- 2 two occurs in order to distinguish which tumors are
- 3 influenced by hormones; right? In other words,
- 4 type ones are typically influenced by hormones,
- 5 type twos are not?
- 6 MR. HEGARTY: Objection to form.
- 7 THE WITNESS: Right.
- 8 BY MR. DEARING:
- 9 Q. And type one endometrial carcinomas,
- 10 which would include endometrioid carcinomas, are
- 11 thought to be influenced by estrogen and other
- 12 hormones; right?
- 13 A. Correct.
- 14 Q. And first let me ask you: It's my
- 15 understanding that that may be somewhat of an
- 16 antiquated distinction or maybe even a distinction
- 17 without as much relevance now as it was when it
- 18 first came out. Do you agree with that suggestion?
- 19 A. No.
- 20 Q. Okay. Good. Are endometrioid ovarian
- 21 cancers susceptible to hormones the way
- 22 endometrial -- endometrioid endometrial cancers
- 23 are?

1 correct?

A. Correct.

A. Correct.

A. That's correct.

19 endometrioid carcinomas --

Q. -- of the ovary?

10 to the ovary?

A. Yes.

A. Yes.

A. Yes.

2

3

5

12

15

20

21

22

23

25

14 ago?

A. Less well proven, but likely.

4 very influenced by hormones; correct?

Q. Serous endometrial cancers are type two;

Q. In other words, they're not thought to be

Q. I'll follow up with that in a minute. So

9 metastasized endometrial cancer that metastasized

Q. And your support for that conclusion is

Q. She was diagnosed at age 37. Would you

13 the criteria that you just went through a minute

17 agree with me that that's 20 years or so younger

18 than the mean age of a woman diagnosed with

Q. Okay. Is there a mean age of women

A. Yes. It's also -- it's also in the 50s.

7 it's your opinion in Balderrama that she doesn't

8 have an ovarian cancer at all, she just has a

- e 1 Q. You stated that her Ms. Balderrama's
 - 2 medical history is significant for obesity,
 - 3 infertility, probable polycystic ovarian syndrome,
 - 4 left salpingectomy due to ectopic pregnancy, and
 - 5 five hysteroscopies with endometrial biopsy. Does
 - 6 any of her medical history as it's described there
 - 7 increase her risk of getting endometrioid ovarian
 - 8 carcinoma, even though I know you're saying that's
 - 9 not what she has. I guess we can break that down.
 - Do you think obesity is a risk factor
 - 11 for endometrioid ovarian cancer?
 - 12 A. Not to my awareness.
 - 13 Q. What about infertility? Is infertility a
 - 14 risk factor for endometrioid adenocarcinoma cancer
 - 15 of the ovary?
 - 16 A. I don't think so, so.
 - 17 Q. What about polycystic ovarian syndrome?
 - 18 A. It is not
 - 19 Q. Do you believe that obesity is a risk
 - 20 factor for endometrial -- endometrioid endometrial
 - 21 carcinoma?
 - 22 A. Yes.
 - Q. And is that because obese woman have
 - 24 excess estrogen, typically?
 - 25 A. Yes.

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- 1 Q. Because estrogen of being stored in the 2 fat cells and that kind of thing.
- 3 A. Yeah, so -- yes.
- 4 Q. And I'm simplifying that --
- 5 A. Yes, you are.
- 6 Q. -- much more than it probably is, but...
- What about those other medical
- 8 findings, the infertility, polycystic ovarian
- 9 syndrome, did those increase her risk of
- 10 endometrial cancer?
- 11 A. Yes.
- 12 Q. All of them? Well, infertility did.
- 13 A. Well, because a significant percentage of
- 14 infertility people have polycystic ovary disease or
- 15 are obese, the association is present with
- 6 : 6 ::1::
- 16 infertility.
- 17 Q. So the infertility may be attributed to
- 18 those other things which make it a risk factor for
- 19 uterine cancer.
- 20 A. You are correct. Which is the bugger
- 21 about associations.
- Q. You talk about her family history here,
- 23 that she has a maternal aunt with possible uterine
- 24 diagnosed with endometrioid endometrial carcinomas 24 cancer, and a maternal great aunt or great
 - 25 grandmother with breast cancer. Neither of those

44 (Pages 170 - 173)

- 1 two family member cancers increased her risk of
- 2 ovarian cancer, did they?
- 3 A. No.
- 4 Q. And you state that she had no genetic
- 5 testing; right?
- 6 A. Correct.
- 7 Q. If she had a full panel of genetic
- 8 testing which proved to be negative, would that
- 9 influence your opinion about her condition at all?
- 10 A. No.
- 11 Q. You just described the criteria that's
- 12 used in your opinion to determine whether this
- 13 ovarian tumor is truly an ovarian cancer or whether
- 14 it's metastasis from the uterus. Were there any
- 15 other observations or considerations that you
- 16 recognized or identified that led to that
- 17 conclusion, or are you basing it solely on the
- 18 criteria that you described?
- 19 MR. HEGARTY: Objection to form.
- 20 THE WITNESS: I am basing it on the
- 21 criteria. It is now well established that whether
- 22 the tumors -- synchronous tumors of the uterus and
- 23 ovary, although they behave in two different ways,
- 24 the molecular biology of these tumors show that
- 25 they're all endometrial metastasis.
- Page 175
- 1 BY MR. DEARING:
- Q. So are you saying it's not possible at3 all that her endometrial tumor could be an ovarian
- 4 metastasis?
- 5 A. Correct.
- 6 Q. Does that just never happen? Why --
- 7 A. It just -- yeah, it -- it just doesn't
- 8 happen.
- 9 Q. Okay. Do you have any opinions about how
- 10 she developed metastatic tumor on her ovary from
- 11 the endometrium?
- 12 A. Sure. There's several roots for it. One
- 13 of them is direct spread through the fallopian
- 14 tubes.
- 15 Q. The same way endometriosis would spread?
- 16 A. Correct. And then the other would be
- 17 through lymphatics.
- 18 Q. Would you agree with me that there is no
- 19 evidence of metastasis anywhere else in her tissue?
- 20 A. To the cervix.
- Q. Oh, there was metastasis to the cervix?
- 22 A. Yes.
- Q. Did you look at those slides --
- 24 A. Yes.
- 25 Q. -- specifically? You also say that other

- Page 176 1 findings include a focus of endometriosis in the
- 2 left ovary that was not originally detected. If
- 3 your opinion is that this was a metastasis of the
- 4 endometrium, the endometriosis did not contribute
- 5 to cause that cancer; correct?
- A. Correct.
- 7 Q. I don't know how clear that question was.
- 8 Let me ask a simpler way. Is it your opinion that
- 9 her endometriosis -- strike that.
- 10 Did Ms. Balderrama's endometriosis
- 11 contribute to cause her cancer?
- 12 A. No.
- 13 Q. Thank you. Should have started with that
- 14 one. I'm getting tired already.
- 15 In preparing your report or reaching
- 16 these opinions, did you read any other expert
- 17 reports, defense expert reports?
- 18 A. No.
- MR. HEGARTY: On that point, David, we
- 20 didn't provide Dr. Felix with Dr. Cramer's reports,
- 21 and he's not had a chance yet to read through
- 22 those. And we anticipate that he would -- he will
- 23 comment on Dr. Cramer's reports as he's commented
- 24 on Dr. Wolf and Dr. Clarke-Pearson's reports via
- 25 supplemental report.

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- 1 And obviously, to the extent that
- 2 we do that and you need some time to ask Dr. Felix
- 3 about his review of that -- Dr. Cramer's reports in
- 4 this case and what he wrote, then we will, I'm
- 5 sure, come to an accommodation about that.
- 6 MR. DEARING: Okay. Thank you.
- 7 MR. HEGARTY: So, yeah, we have provided
- 8 to Dr. Felix Dr. Cramer's report.
- 9 THE WITNESS: I think he said defense.
- 10 MR. DEARING: I did say defense, but I
- 11 was going to ask plaintiff.
- MR. HEGARTY: You're right. I jumped the
- 13 gun.
- 14 MR. DEARING: That's okay.
- 15 BY MR. DEARING:
- 16 Q. And with regard to plaintiff expert
- 17 reports, you've read Dr. Godleski's report; right?
- 18 A. Correct.
- 19 Q. And you've not had a chance to read
- 20 Dr. Cramer's report but you intend to?
- 21 A. Yes.
- Q. You state in this middle paragraph on
- 23 page 5, "Within the last ten years, molecular
- 24 genetic data have accumulated to support the
- 25 current understanding that the vast majority of

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1

2

- 1 these synchronous primary tumors are clonal in
- 2 nature and represent metastatic endometrial
- 3 cancer."
- 4 Isn't it true that you can't
- 5 definitively establish clonal cells without doing
- 6 clonal testing?
- 7 A. That's what they did.
- 8 Q. Right. But that wasn't done in this
- 9 case --
- 10 A. Oh, no, not in this case.
- 11 Q. -- in Balderrama.
- 12 A. I'm sorry. Yes.
- 13 Q. You state that these metastatic
- 14 endometrial tumors behave clinically like low-stage
- 15 neoplasms and carry a better prognosis than typical
- 16 stage 3A metastatic uterine carcinomas. Then you
- 17 say, "This may be due to restricted dissemination
- 18 of tumor cells through fallopian tubes rather than
- 19 metastasis through myometrial or lymphovascular
- 20 invasion." Can you just explain that sentence for
- 21 me? What is restricting dissemination through
- 22 fallopian tubes?
- A. I'm sorry, I didn't -- I hope I didn't
- 24 say that. No. What I'm saying in that sentence is
- 25 that the different behavior, meaning if they're all

- 3 Q. How do they move?
- A. Through -- through cell membrane
- 5 undulations. There's actually assays that you can
- 6 do to test for that.

Q. Really?

A. Yeah.

- 7 Q. Okay. I learn something every
- 8 deposition.
- 9 A. Me too.
- 10 Q. To be clear, is it your opinion that the
- 11 endometrial cancer metastasized to the ovary
- 12 through the fallopian tubes, or do we not know?
- A. I do not know. In this case I know that
- 14 I did not find lymph vascular space involved in the
- 15 tumor. So possibly, but I -- you don't need to
- 16 detect lymph -- sorry. You can have cases in which
- 17 you cannot see lymph vascular space involvement in
- 18 the uterus where metastases to lymph nodes and
- 19 other organs are present.
- 20 Q. Are you able to opine one way or the
- 21 other which method of transport was most likely
- 22 given the facts of this case?
- 23 A. I cannot.
- 24 Q. In your general section entitled talc and
- 25 ovarian cancer on page 7, the first sentence of

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- 1 metastatic because of clonal determinations, all of
- 2 them are clonal, then why do they behave
- 3 differently. And the reason these authors
- 4 postulated was that it was probably because the
- 5 tumor cells went to the ovary through the fallopian
- 6 tube rather than metastases through lymphatic or 7 hematogenous spread. So that may explain why these
- 8 tumors behaved better than stage three endometrial
- 9 cancer.
- 10 Q. How is the method by which they got there
- 11 make any difference in how they behave or respond?
- A. Because dissemination to lymph nodes and
- 13 other organs occurs in -- with endometrial cancer
- 14 occurs almost exclusively by lymphatics. If the
- 15 tumor has not learned how to get into lymphatics,
- 16 then it will not metastasize. But if it does go
- 17 into the ovary through the fallopian tube, it
- 18 didn't need to learn how to metastasize yet.
- Q. Well, obviously those tumor cells don't
- 20 have a means of motility, so are they swept up into
- 21 the fallopian tube the same way through retrograde
- 22 menstruation, or how do they get there?
- 23 A. Correct, through retrograde menstruation.
- 24 Q. Okay.
- 25 A. By the way, tumor cells are motile.

Page 181 1 that section states that while some retrospective

- 2 case control studies have suggested a weak
- 3 association between perineal talc exposure and
- 4 ovarian cancers, others have not.
- And my question is just in the world
- 6 of epidemiology, weak is sort of a term of art.
- 7 What -- what relative risk or hazard ratios are you
- 8 considering weak?
- 9 A. Under two.
- 10 Q. Anything under two is weak?
- 11

14

- 12 Q. And then anything over two, would that be
- 13 moderate or strong or --
 - MR. HEGARTY: Object to form.
- 15 THE WITNESS: Yeah, moderate or
- 16 indeterminate.
- 17 BY MR. DEARING:
- 18 Q. Okay. So in your opinion any relative
- 19 risk under two is weak?
- 20 A. Yes.
- 21 Q. Okay. Have you done any of the research
- 22 involving endocrine disrupting chemicals and their
- 23 association with uterine cancers?
- 24 A. No. I don't even know what an endocrine
- 25 disrupting chemical is.

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Q. Okay. In the next section on page 9 is 2 where you start responses to plaintiff experts.

3 And this section really is just in response to

4 Dr. Godleski's findings.

In most and possibly all of these

6 reports you make the statement that none of this 7 birefringent material was subjected to SEM EDS

8 analysis to determine if it is compositionally

9 consistent with talc or if, more likely, it is

10 consistent with the 477 non-talc particles

11 identified by SEM EDS in Ms. Balderrama's two 11 other words, do you just get that report e-mailed

12 pathology specimens.

13 If talc is ubiquitous, why is it more

14 likely that those particles, those birefringent

15 particles, are not talc?

A. Okay, so you've used that term several

17 times, ubiquitous.

18 Q. Right.

19 A. What -- what are you -- what are you

20 intending to mean by that?

Q. Let me just ask it more generally. Why

22 is it more likely -- why are you using the phrase

23 "more likely" there to describe that the

24 birefringent particles are more likely the non-tale 24

25 particles versus talc?

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- A. By Dr. Godleski's own data. His -- his
- 2 -- he discovered more non-talc particles than talc 3 particles.
- 4 Q. Did you look at his data to read what
- 5 those non-talc particles were?

A. I don't think he discloses that in his

7 report.

Q. I don't know if it's in his report. It's

9 usually in his data, though, that we send with the

10 report, the data files.

So -- well, let me ask you. When you

12 were provided Dr. Godleski's report, were you also

13 provided the Dropbox link that had all of his data

14 files in it?

- 15 A. I don't believe so.
- 16 Q. Okay. Would that be true of all these

17 cases?

- 18 A. I know that I received additional images,
- 19 but I don't think I saw raw data.
- Q. Okay. Like SEM spectra, you don't think
- 21 you've looked at those?
- 22 A. Only the ones in his report.
- Q. Okay. Well, I was going to ask you
- 24 whether examples of those other 40 -- 477 non-talc
- 25 particles are things that you would typically find

1 in a pathology lab that would contaminate tissue

2 the way you say talc is a contaminant. But without

3 knowing what those particles are, I guess you can't

4 answer that question.

5 A. I can't.

6 Q. So logistically, or just practically

7 speaking, when Johnson & Johnson's attorneys

8 provide you with Dr. Godleski's report, do

9 they -- are they not also providing you all of the

10 data points that -- that were provided to them? In

12 to you, or how does that work?

A. Yeah, I don't remember whether it was in

14 a Box file or whether it was sent to me by e-mail.

15 I just don't remember. Likely in a Box file, it's

16 been their habit and custom.

Q. A box file. You mean Dropbox, or are you 17

18 talking about a hard copy?

19 A. Well, there's Dropbox and Box. They're

20 similar file sharing.

21 Q. But you're talking about electronic

22 transmission --

23 A. Yes.

Q. -- not hard copies. Okay. Do you have

25 any way of opining whether those 477 non-talc

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1 particles are lab contaminants?

A. They would have to be because there is no

3 foreign body reaction to them.

4 Q. Well --

A. So the -- so they can't be -- have been

6 particles acquired by the patient while the ovary

7 was vital, meaning not removed.

Q. So presumably we're talking about

9 exogenous materials here as these contaminants,

10 exogenous meaning they're not naturally occurring

11 inside the body?

12 A. Correct.

13 Q. Would you agree with me that there are

14 endogenous materials that would evoke an

15 inflammatory reaction like macrophages? And we

16 mentioned one of them already, dead cancer cells.

17 A. Yes.

18 Q. Calcium, for example, may elicit an

19 inflammatory reaction; right?

20 A. Most calcium deposits do not elicit an

21 inflammatory reaction.

22 Q. Okay. What about the presence of iron,

23 would iron in an adequate quantity elicit an

24 inflammatory response?

25 A. Some forms of iron would, yes. And he

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- 1 does provide some -- some information about that in
- 2 his report. He says a total of 486 particles were
- 3 found, and analyzed tissues may have carbonaceous
- 4 material detected in backscatter electron
- 5 microscopy mode.
- Q. Right. Most of the carbon he's referring 7 to is endogenous; right?
- MR. HEGARTY: Objection to form. 8
- 9 BY MR. DEARING:
- 10 Q. I mean, tissue is made up mostly of
- 11 carbon, isn't it?
- 12 A. Not -- not elemental carbon, though.
- 13 O. Okay.
- 14 A. Dr. Godleski's making assumptions in that
- 15 paragraph.
- Q. Which paragraph? 16
- 17 A. The one that I was reading from.
- 18 Q. What do you mean? Can you just tell me
- 19 what --
- 20 A. Sure. He says the fact that
- 21 calcification is frequently found in ovarian cancer
- 22 and often readily seen by line microscopy supports
- 23 the likelihood of many particles having that
- 24 composition. I mean, the calcification seen in
- 25 ovarian cancer are -- are not refringent.
- Page 187
- Q. Okay. I thought he was talking about
- 2 SEM. Particles identified by SEM, not birefringent 3 particles.
- A. Well, the ones that he's -- does SEM on
- 5 are refringent.
- Q. Can you see refringence in SEM?
- 7 A. No.
- Q. Okay. So he's identifying particles with
- 9 SEM, but he's not commenting on their refringent
- 10 properties; right?
- 11 MR. HEGARTY: Objection to form.
- 12 THE WITNESS: He does both. He comments
- 13 on the refringence on the H&E, and then he comments 13
- 14 on the composition by SEM.
- 15 BY MR. DEARING:
- Q. Right. But the particles he's
- 17 identifying as calcium he's identifying by SEM,
- 18 which are not birefringent and not polarized;
- 19 right?
- 20 A. Well, he says carbonaceous, not carbon;
- 21 right? Yes.
- Q. Well, I thought you were talking about
- 23 calcium. Okay, let me move on.
- Would you agree that microscopists'
- 25 ability to see and evaluate the depth and

- Page 188 1 orientation and cellular contents is better when
- 2 you're actually looking into the micrograph -- I
- 3 mean looking into the microscope as opposed to when
- 4 you're looking at a two-dimensional micrograph?
- A. Yes.
- 6 Q. At the bottom of page 9 in that paragraph
- 7 you state, "Dr. Godleski uses SEM to determine the
- 8 relative chemical composition of particulate
- 9 material on the surface of the processed tissue
- 10 specimens."
- And I've already suggested to you
- 12 that's not what he's doing, that he's using
- 13 pressure -- variable pressure SEM to look below the
- 14 surface. Then you say, "His SEM images do not
- 15 provide enough detail to identify the nature of the
- 16 cells present in any of the particulate matter --
- 17 particulate material being analyzed."
- 18 Would you agree that looking directly
- 19 at the SEM images as they occur in the instrument
- 20 will give you a more detailed and better vantage
- 21 point than looking at two-dimensional photographs?
- 22 MR. HEGARTY: Objection to form.
- 23 THE WITNESS: I don't know.
- 24 BY MR. DEARING:
- 25 Q. We did not receive any invoices

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- 1 associated with the Balderrama case. This case has
- 2 been pending for many years. Have you invoiced the
- 3 lawyers for Johnson & Johnson at all in this case
- 4 yet?
- 5 A. Not to the best of my knowledge, no.
- Q. Do you know when you first started
- 7 working on this Balderrama report?
- A. I don't recall.
- Q. Would it have been in the last two years,
- 10 or did you start on it eight years ago or so when
- 11 we first started litigating Balderrama?
 - A. Was this part of the MDL group?
 - Q. Nope.
- A. No. 14

12

- 15 Q. This is a New Jersey state court?
- MR. HEGARTY: You don't need to look 16
- 17 anything up right now, but --
- 18 THE WITNESS: Yeah, I don't recall.
- 19 BY MR. DEARING:
- 20 Q. Do you recall whether you participated in
- 21 a Kemp hearing, which is a -- like a Daubert
- 22 hearing in New Jersey, in Atlantic City?
- 23 A. No, I did not.
- 24 Q. So as you sit here now, to your
- 25 knowledge, you've never created any invoices in the

Page 190

- 1 Balderrama case?
- 2 A. Correct.
- 3 Q. Did the lawyers for Johnson & Johnson
- 4 send you the tissue blocks associated with
- 5 Ms. Balderrama's case?
 - A. They did not.
- 7 Q. Did you request to see them?
- 8 A. I did not.
- 9 Q. Did you maintain any copies of the chain
- 10 of custody paperwork that traveled with the slides?
- 11 A. I don't remember.
- 12 Q. Okay. Moving on to Ms. Rausa. And for
- 13 your reference, the rest of these cases are in the
- 14 MDL.
- 15 A. Okay. Thank you.
- 16 Q. The first two were in New Jersey state
- 17 court.
- So first, does your report contain all
- 19 of your opinions that you intend to offer in this
- 20 case?
- 21 A. Yes.
- 22 Q. Are there any materials not listed on
- 23 your reference list that you're relying on for your
- 24 opinions in this matter?
- 25 A. No.

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- 1 Q. And what did Johnson & Johnson's lawyers 2 ask you to do in this case?
- A. They asked me to examine the pathology
- 4 for -- to determine tumor type, stage, and whether
- 5 there was any evidence that talc may have
- 6 contributed to the genesis of the neoplasm.
- 7 Q. In your opinion, was Ms. Rausa's cancer 8 properly diagnosed by her treating pathologist?
- 9 A. I'll take one second here, please. Yes, 10 they did.
- 11 Q. And do you disagree with any of the
- 12 statements and opinions of Ms. Rausa's treating
- 13 pathologist?
- 14 A. I did not.
- 15 Q. I should ask that more broadly. Do you
- 16 disagree with any of the statements or opinions of
- 17 any Ms. Rausa's treating physicians?
- 18 A. Not that I can recollect.
- 19 Q. In her clinical history, you state that
- 20 she was diagnosed with stage 3A2 high-grade serous
- 21 carcinoma of her right and left ovaries. Is that
- 22 your understanding of her diagnosis? In other
- 23 words, do you agree with that diagnosis?
- 24 A. Yes.
- Q. Okay. Later in that same paragraph you

1 state that genetic panel testing did not identif

- 1 state that genetic panel testing did not identify
- 2 known pathogenic germline mutations, though she was
- 3 found to have a variant of uncertain significance.
- 4 Would you agree that nothing in her
- 5 panel testing or tumor testing showed that she has
- 6 a genetic mutation or any other finding known to
- 7 increase her risk of ovarian cancer?
- A. Correct.
- Q. You state that her family history is
- 10 unremarkable for cancer. Is it a fair statement to
- 11 say that there's nothing in her family history
- 12 that, as far as you know, would have increased her
- 13 risk of ovarian cancer?
- 14 A. That is correct.
- 15 Q. To your knowledge, does she have any
- 16 co-morbidities or other health conditions that may
- 17 have increased her risk of getting high-grade
- 18 serous carcinoma?
- 19 A. No.
- 20 Q. You make this recurring sentence in your
- 21 reports on page 5, second paragraph, about three or
- 22 four sentences in, you say, "In the absence of an
- 23 associated foreign body reaction, including the
- 24 presence of foreign body giant cells and/or
- 25 particle-laden macrophages, foreign materials in
- Page 193
- 1 processed histology specimens is widely agreed by
- 2 pathologists to be simple particulate contaminant
- 3 introduced into the tissue at the time of surgical
- 4 removal and/or tissue processing for histologic
- 5 examination."
 - When you say it's widely agreed, what
- 7 source are you relying on for that, or is that just
- 8 your personal experience?
- 9 A. Yes, it's my -- my conversation with
- 10 many -- many, many pathology colleagues.
- 11 Q. Can you point to any publications
- 12 that -- or sources -- that suggest that if talc is
- 13 found in tissue where there's no evidence of
- 14 foreign body reaction, it has to be contamination?
- 15 A. I have referenced articles in which the
- 16 authors state that there must -- that talc elicits
- 17 a foreign body reaction. So if you don't see a
- 18 foreign body reaction, then it has to have gotten
- 19 in the tissue after it was devitalized.
- 20 Q. You go on to say, "The only foreign
- 21 particles identified within macrophages in
- 22 Ms. Rausa's histology specimens were observed

23 sequestered within the cytoplasm of macrophages in

- 24 the left external iliac and periaortic lymph
- 25 nodes." Was that an observation of her clinical

Page 194 Page 196 1 pathologist? 1 whose sister was -- had a confirmed diagnosis of A. You mean the pathologist at the 2 breast cancer; right? 3 hospital --3 A. Correct. 4 4 Q. Yes. Q. And that's a pretty large database, isn't 5 A. -- the treating? No, it was not. 5 it? Q. Okay. So that was -- was that an A. It's not as large as the women's health 6 7 observation you made? 7 initiative, but it's fairly large. 8 A. Yes. 8 Q. I mean, since you cited that study in Q. Where is the left external iliac and 9 every report, do you believe that -- that that 10 periaortic lymph nodes? 10 database that that study derives from is a -- is a A. The external iliac artery vein in the 11 good and reliable database? 12 lymphatic chain is the -- a branch of the aorta. 12 MR. HEGARTY: Objection to form. 13 It goes from common iliac to external iliac, which 13 THE WITNESS: I think it's as good as it 14 goes to perfuse the leg, and the internal iliac 14 gets. 15 that goes to perfuse bladder, part of the rectum, 15 BY MR. DEARING: 16 and the genital organs. So it is in the external Q. Okay. Do you think the authors with 16 17 iliac would be the divergence of the common iliac 17 Dr. O'Brien -- do you think Dr. O'Brien and her 18 to the artery that would go towards the leg. 18 co-authors are able to fully evaluate and interpret 19 the data gathered from the sister study?

20

22

24

19 Q. Okay. So does the pelvic -- does the 20 pelvis drain into those lymphatic -- those lymph

21 nodes?

22 A. Parts of the pelvis can. The external

23 iliac usually associated with -- with vulva, vagina

24 and cervix more than with uterus and ovary. Those

25 would have more of a tendency to go to the internal

Page 195

1 iliac. They can also both go to the common iliac,

2 and they can both go to the periaortic.

3 Q. Did you polarize those particles?

4 A. Yes.

5 Q. Were they birefringent?

6 A. Yes, they were refringent.

7 Q. Do you have an opinion about how they got

8 there?

9 A. I have opinions on how they can get

10 there. So they can get there through abrasions of

11 the skin of the perineum, vulva. They can be

12 particles that -- that were put there in the pelvis

13 for some reason.

14 Q. Do you have an opinion about how these

15 particular particles got there?

16 A. I have no certainty as to how they got

17 there, no.

Q. On page 7 in the top paragraph where

19 you're discussing Dr. Clarke-Pearson's

20 opinions -- that's Clarke, C-L-A-R-K-E, hyphen

21 P-E-A-R-S-O-N -- you reference the O'Brien 2020

22 study. And as I recall, that's a study that relied

23 on the sister study data; right?

A. I believe so, yes.

Q. The sister study being a study of women

1 you cite to them.

21 for speculation.

23 BY MR. DEARING:

A. Yes, I know one of those authors very

THE WITNESS: Well, they did.

25 I mean, you trust their opinions about it? 'Cause

Q. Right. But you think they did it well?

MR. HEGARTY: Objection to form. Calls

Page 197

3 well. He's a very responsible, careful person.

Q. Which one do you know?

5 A. Nico Winstonson.

6 Q. Winstonson. Okay. In the next one you

7 state, "When evaluating the prospective cohort

8 studies, there is no association between talc use

9 and the development of ovarian cancer." I've

10 already asked you that question.

In Ms. Rausa's case, those particles

12 that you identified in macrophages were

13 birefringent. Is it possible those are talc

14 particles?

15 A. Anything is possible. They could be talc

16 particles, sure.

17 Q. So when you say in the same paragraph, "I

18 have not encountered talc foreign body reactions

19 since surgeons stopped using talc and other

20 powders," is that partly because you've never

21 identified the particle itself that was associated

22 with the reaction like the particle that was

23 engulfed by a macrophage?

24 A. Because I didn't what?

25 Q. So you're saying --

50 (Pages 194 - 197)

1 MR. HEGARTY: Object to form.

2 BY MR. DEARING:

- Q. You write, "Despite the common use of
- 4 perineal talc, I have not encountered talc foreign
- 5 body reactions since surgeons stopped using talc
- 6 and other powders as lubricants for surgical7 gloves."
- 8 But you testified in Ms. Rausa's case
- 9 you did identify foreign particles that were
- 10 birefringent in macrophages. But you say --
- 11 A. In the lymph node.
- 12 Q. In the lymph node.
- 13 A. So I was referring, but with that
- 14 sentence, as to my examination of tens of thousands
- 15 of ovaries.
 - Q. So in the tens of thousands of ovaries
- 17 you've looked at, you've never seen a foreign
- 18 particle sequestered by a macrophage, or you have,
- 19 or a granuloma?
- 20 A. Not something that could be talc. I've
- 21 seen it to -- I've seen it to suture material.
- 22 I've seen it to teratomatous components. But not
- 23 something that would be consistent with talc.
- Q. Well, using a routine light microscope,
- 25 the only thing you could say about the particle

le.

- Page 199
- 1 that was consistent with talc is that it might be
- 2 birefringent if you polarized it; right?
- 3 A. Correct, but -- well, that it
- 4 could -- yeah. And then it had the right
- 5 appearance, right?
- 6 Q. So are you saying that you've never seen
- 7 a foreign particle in the gynecologic tissue that
- 8 was associated with a foreign body reaction?
- 9 A. No, I just said that I have, but
- 10 not -- but not refringent particles that would be
- 11 consistent with talc.
- 12 Q. Okay. But you would agree that you
- 13 haven't polarized most of the slides you study;
- 14 right?
- 15 A. I don't need to. Because if there's no
- 16 reaction to it, then you wouldn't --
- 17 Q. Okay, we're -- I think we're talking in
- 18 circles. I'm trying to clarify what your testimony
- 19 is.
- Are you saying that in your vast
- 21 experience you have not observed a particle except
- 22 for -- and I don't consider suture material a
- 23 particle. I'm just talking about a -- for purposes
- 24 of this question, it's a foreign particle, not
- 25 suture material, not anything endogenous. Are you

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- 1 saying you've never encountered a foreign particle 2 in gyn tissue associated with an inflammatory
- 3 response to it or a foreign body reaction?
- 4 MR. HEGARTY: Objection to form.
- 5 THE WITNESS: Correct.
- 6 BY MR. DEARING:
- 7 Q. Okay. Well, at least not since surgeons
- 8 stopped dusting their gloves with talc?
- A. Correct.
- 10 Q. You state also in that same paragraph a
- 11 little further down, "Cell culture studies of
- 12 potential cancer-causing inflammatory mediators
- 13 must be validated in animal models and humans
- 14 before any causal assumptions can be made."
- 15 Animal models maybe, but you can't do
- 16 a cell culture in a human where the potential
- 17 outcome may be cancer; right? That's a nonstarter.
- 8 A. There's accidental exposures too.
- 19 We've -- we have done many studies in humans that
- 20 have been exposed to potentially carcinogenic
- 21 materials that are acquired by the human by
- 22 accidental exposure. So you don't need to do a
- 23 prospective study exposing the human, but you can
- 24 certainly evaluate humans who have been exposed.
- Q. How could a woman have been accidentally
- n

- 1 exposed to talc such that it would be implanted in
- 2 her -- on her ovary or fallopian tube?
- 3 A. I don't think --
- 4 MR. HEGARTY: Objection to form.
- 5 THE WITNESS: -- she can.
- 6 BY MR. DEARING:
- 7 Q. Right. So that's a human experiment that
- 8 can never happen?
- 9 A. Correct.
- 10 Q. All right. So by that logic you're
- 11 saying these cell culture studies can never be
- 12 validated by human study?
- 13 A. Not after the exposure of the ovaries to
- 14 dusted gloves.
- 15 Q. Okay. We requested -- as we've
- 16 discussed -- in our notice of deposition that you
- 17 provide invoices for this case. And we didn't
- 18 receive any. Does that mean that no invoices have
- 19 been created in this case?
- 20 A. That's correct.
- Q. Do you know whether you retained a copy
- 22 of the chain of custody forms that traveled with
- 23 these slides? And I'll tell you with the MDL
- 24 cases, there are chain of custody forms with all of
- 25 them.

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- A. I don't recall, but likely yes. And I
- 2 did not bring them with me.
- 3 Q. Did you -- I'm sorry. Strike that.
- 4 Did the lawyers for Johnson & Johnson
- 5 send you any of Ms. Rausa's tissue blocks?
- A. They did not.
- 7 Q. Did you request any of her tissue blocks?
- 8 A. I did not.
- 9 Q. Do you have any opinions as to what
- 10 caused Ms. Rausa's ovarian cancer?
- 11 A. Yes.

1

- 12 Q. What is that opinion?
- 13 A. I believe that Ms. Rausa's cancer is a
- 14 sporadic ovarian -- high-grade serous ovarian
- 15 cancer.
- 16 Q. By sporadic, do you mean it was caused by
- 17 irregular replication of cells?
- 18 A. Mistake in the replication of cells.
- 19 Q. And is it your opinion that she has no
- 20 risk factors for ovarian cancer?
- 21 A. Yes.
- 22 Q. Okay. Next case is Converse.
- 23 THE WITNESS: I'm going to take three
- 24 minutes.
- 25 MR. DEARING: All right.

1 treating physicians, including her pathologist?

- 2 A. No, not that I recollect.
- 3 Q. Is the -- I'm sorry. Strike that. Is
- 4 Ms. Converse's usage of Johnson's baby powder
- 5 relevant to your opinions in this case?
- 6 A. It is not.
- 7 Q. Did you identify any risk factors for
- 8 Ms. Converse that may have contributed to her
- 9 ovarian cancer? Just specifically you say her
- 10 family history includes breast cancer diagnosed in
- 11 her mother at age 46, as well as in a paternal aunt
- 12 in her 70s, and a paternal cousin in her 40s. And
- 13 then pancreatic cancer in her maternal grandmother
- 14 at age 87, non-Hodgkin's lymphoma diagnosed in a
- 15 maternal uncle in his 70s, and lung cancer in her
- 16 father in his 80s.
- 17 A. That's --
- 18 Q. Do any of those family histories place
- 19 Ms. Converse at an increased risk of getting clear
- 20 cell carcinoma of the ovary?
- 21 A. Well, her -- her -- her two factors that
- 22 would increase the risk of ovarian cancer in her
- 23 case would be the fact that she's an Ashkenazi Jew,
- 24 and that her mother had breast cancer at age 46.
- Q. Is her mother's breast cancer a risk

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- 1 (Break taken.)
- 2 BY MR. DEARING:
- 3 Q. Doctor, if you would now look at your
- 4 Converse report.
- 5 A. Yes.
- 6 Q. Incidentally -- well, does your report
- 7 contain all of your opinions you intend to offer in
- 8 this case?
- 9 A. Yes.
- 10 Q. Are there any materials not listed on
- 11 your reference list that you're relying on for your
- 12 opinions in this matter?
- 13 A. No.
- 14 Q. And what exactly did Johnson & Johnson's
- 15 lawyers ask you to do in this case?
- 16 A. I was asked to evaluate the pathology of
- 17 Ms. Converse's ovarian tumor, classify it, stage
- 18 it, and determine if any foreign material may have
- 19 contributed to the genesis of her neoplasm.
- Q. In your opinion, did Ms. Converse's --
- 21 was Ms. Converse's cancer properly diagnosed by her 21
- 22 treating pathologist?
- A. Yes, it was.
- 24 Q. Do you disagree with any of the
- 25 statements or opinions of any of Ms. Converse's

- 1 factor specifically for clear cell carcinoma or is
- 2 it a risk factor for just ovarian cancers in
- 3 general?
- 4 A. It's a risk factor for ovarian cancer in
- 5 general.
- 6 Q. There are no studies that suggest that a
- 7 patient's mother's breast cancer increases her risk
- 8 of clear cell carcinoma, is there?
- 9 A. Yeah, I don't -- I don't remember whether
- 10 they exclude clear cell from any cancer. So when
- 11 lumped into a pool, I'm not sure that you can say
- 12 that it -- it doesn't have some influence. But the
- 13 percentage of clear cell carcinomas -- the
- 14 percentage of ovarian cancer that is -- are
- 15 composed of clear cell carcinomas is small.
- 16 Q. Right.
- 17 A. So the data obviously is more predictive
- 18 of serous carcinomas.
- 19 Q. Do you know why Ashkenazi Jewish ancestry
- 20 increases a women's risk of ovarian cancer?
- 21 A. They have more inherited -- inherited
- 22 mutations.
- Q. And of course you're aware that
- 24 Ms. Converse got a full panel genetic testing done;
- 25 right?

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3

- A. Correct. 1
- 2 Q. And would you agree that her panel
- 3 testing showed that -- I'm sorry. Strike that.
- 4 Would you agree that her genetic
- 5 testing failed to identify any detectable
- 6 pathogenic mutations?
- 7 A. I agree.
- Q. And that her -- do you agree that her
- 9 genetic testing did not show any germline mutations
- 10 or any other findings that are known to increase a
- 11 women's risk for ovarian cancer?
- 12 A. I agree.
- 13 Q. The germline mutations that increase a
- 14 woman of Ashkenazi descent's risk of ovarian cancer
- 15 are included in these panel testings; right?
- A. I believe so, yes.
- 17 Q. Right?
- 18 A. Of the known ones.
- 19 Q. And she tested negative for all of them;
- 20 correct?
- 21 A. Correct.
- 22 Q. On page 5, under the photographs in your
- 23 report, you state that areas of Ms. Converse's
- 24 tumor had definitive evidence of non-neoplastic
- 25 endometriotic tumor within the cystic.

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- MR. DEARING: And at this point I need to 1
- 2 take a pause. Let's go off the record for a
- 3 second.
- 4 (Break taken.)
- MR. DEARING: Back on the record. I'm
- 6 going to mark as Exhibit 6 your Brandi Carl report.
- 7 (Exhibit 6 marked for identification.)
- MR. DEARING: And Exhibit 7 is going to
- 9 be the Balderrama report. Number 8 will be the
- 10 Rausa report. Except that I'm missing part of it.
- 11 I'm going to mark this as 8, but this is just the
- 12 appendixes. The substance of his report I'll have
- 13 to come back to it. Anyway, 8 will be the Rausa
- 14 report.
- 15 9 will be Converse. 10 will be
- 16 Gallardo. 11 will be Judkins. 12 will be
- 17 Bondurant. Okay.
- 18 BY MR. DEARING:
- Q. And going back to Converse now, on page 5
- 20 of your report, you state that, "Areas of
- 21 Ms. Converse's tumor had definitive evidence of
- 22 non-neoplastic endometriotic tissue within the
- 23 cystic tumor. Is that non-neoplastic endometriotic
- 24 tumor pictured in one of the pictures on page 5?
- 25 A. No, it's pictured on page 6, 7, 8 and 9.

- Page 208 Q. Okay. Can I get you to use my copy of
 - 2 your report that's marked as Exhibit Number 9 --
 - A. Yes, you may.
 - 4 Q. And can you -- I know you've circled it
 - 5 with the computer. On figure two on page 6 you
 - 6 state, "Low magnification view of the section of
 - 7 Ms. Converse's clear cell carcinoma. The circled
 - 8 area contains a fossa of endometriosis."
 - 9 Can you be more specific in that
 - 10 circle and identify where the endometriosis is?
 - 11 A. Yes, I can.
 - 12 Q. I'm just going to watch.
 - 13 A. I will point with arrows. The inside of
 - 14 this cystic space --
 - 15 Q. Okay.
 - 16 A. -- is partly depicted in the high
 - 17 magnification below.
 - Q. Okay. And which part of that circle on
 - 19 top is the bottom photograph? 'Cause I couldn't
 - 20 tell. Nothing looked oriented like that to me.
 - 21 A. I believe it's near this arrow.
 - 22 Q. You're pointing to the upper left-hand
 - 23 corner --
 - 24 A. Yes.
 - 25 Q. -- arrow? You say you believe. Are you

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- 1 certain that that's part of it?
 - 2 A. Well --
 - 3 O. 'Cause it doesn't look like that to me.
 - 4 but --
 - 5 A. It's within this -- it's within this
 - 6 cystic space for sure.
 - Q. Then looking -- looking at the bottom
 - 8 photo, can you identify the part of it that is an
 - 9 endometrioid epithelium?
 - 10 A. Yes, I can.
 - 11 Q. Could you circle what that looks like?
 - 12 A. Okay. The endometriosis epithelium. You
 - 13 want me to circle to it?
 - 14 Q. Or put an arrow.
 - 15 A. It's this part over here. The entire
- 16 lining of it. It's a little interrupted there, but
- 17 it continues there.
- 18 Q. Okay. Actually, let's do this. Let me
- 19 give you my highlighter. That might be easier now
- 20 that you circled it.
- 21 A. Too late.
 - Q. Okay.
- 23 A. It's actually more accurate with a pen.
- 24 Q. Okay. And then can you identify the
- 25 endometrioid stroma?

22

2 composition products of blood.

4 would attract a macrophage?

6 are viewed as foreign body.

A. Hemosiderin is one of the -- the

Q. So what is it about a hemosiderin that

A. Oh, certain types of -- of ferric ions

Q. What's the size of those hemosiderin

A. Oh, they can be tiny, sub-one micron.

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Page 210

- A. Yes. It's most prominent over here, but 2 it's present throughout.
- Q. For the record, you're using arrows to --
- 4

1

- 5 Q. -- identify the endometrioid stroma.
- 6 Okay. You can leave it there. I can see it.
- A. This is the best area. 7
- Q. You also reference on page 5, "These
- 9 findings indicate that the cyst in which
- 10 Ms. Converse developed clear cell carcinoma began
- 11 as an endometrioma, and that her cancer arose
- 12 within and from it."
- 13 Is that endometrioma tissue where the
- 14 cancer arose, is that what you were identifying? I
- 15 mean, have you circled that part of it or --
- A. Yes, part of it. This would be -- if you
- 17 looked at only this image, this cystic space here,
- 18 and this higher magnification appearance, you would
- 19 call that endometrioma, not clear cell carcinoma.
- 20 Q. Okay.
- 21 A. It has no feature of malignancy. It has
- 22 no clear cytoplasm.
- Q. And so how do you know that the clear
- 24 cell carcinoma began as an endometrioma and that
- 25 her cancer arose from it?

10 Seldom do they get -- would they even come close to

8 molecules or particles?

- 12 Q. It's a protein, hemosiderin?
- 13 A. Yes.

11 being a micron.

7

- 14 Q. The endometriosis -- sorry if I missed
- 15 this. The endometriotic tissue within the cystic
- 16 tumor, is that on the ovary?
- 17 A. Yes.
- Q. So the endometriotic tissue that got
- 19 there, did it get there the same way that
- 20 endometriosis occurs --
- 21 A. Yes.
- 22 Q. -- that we've been discussing? So why is
- 23 it that sometimes it forms a cyst and sometimes it
- 24 forms endometriosis?
- 25 We don't know.

- A. Well, if you -- if you look at image
- 2 figure number six -- I'm sorry, seven and
- 3 eight -- we have the transition between the
- 4 endometrioma and the clear cell carcinoma.
- Q. Okay. Can you circle where that -- or 6 highlight, or however you want to do it.
- A. So the highlighted area is endometrioma,
- 8 whereas from here on you start seeing more
- 9 proliferative-type epithelium, meaning it's
- 10 stratifying, becoming -- there are more cells per
- 11 area. And then a few cells later, the cells start
- 12 acquiring cleared cytoplasm. And then a few
- 13 microns away you start getting malignant change of
- 14 the epithelial cells as the nucleus and cytoplasm
- 15 are cleared -- sorry -- the nucleus and large and
- 16 cytoplasm cleared.
- 17 Q. Okay. On page 7 you mention
- 18 hemosiderin-laden macrophages. Can you just
- 19 identify where those are in figure four?
- 20 A. Yes. It's much easier in the colored
- 21 photographs, but there, there, over here.
- Q. Okay. How do you know that that's
- 23 hemosiderin?
- 24 A. By its morphological appearance.
- 25 Q. What is hemosiderin?

- Page 213 Q. Did Ms. Converse's treating pathologist
- 2 make any reference to endometriotic tissue being
- 3 associated with the cyst and her endometriosis
- 4 endometrioid -- I mean her clear cell carcinoma?
- A. She does not.
- Q. But you're looking at the same slides
- 7 that she looked at; right?
- A. Yes. The important diagnosis is the 8
- 9 clear cell carcinoma.
- 10 Q. But like you said before, it is also
- 11 important to diagnose endometriosis or similar
- 12 co-morbidities if they exist; right?
- A. In my opinion, it is important, but
- 14 clearly there's a clear cell carcinoma in that
- 15 cyst. You can -- most pathologists will mention,
- 16 you know, arising in the endometrioma. But some
- 17 pathologists may not think that that's important.
- 18 Q. Did Ms. Converse's use of Johnson's baby
- 19 powder impact your opinion at all in this case?
- 20 A. No.
- 21 Q. Did you make any new slides in this case?
- 22 A. I did not.
- 23 Q. Did the lawyers for Johnson & Johnson
- 24 send you the tissue blocks in this case?
- 25 A. They did not.

- Q. Did you request the tissue blocks?
- 2 A. I did not.

1

- 3 Q. Do you intend to comment on any other
- 4 slides or features that aren't articulated in your
- 5 report and in those photomicrographs?
- A. I do not intend to do that.
- 7 Q. Is the endometriotic cyst considered a
- 8 type of endometriosis, or it's just sometimes the
- 9 endometrial tissue forms a cyst and sometimes it
- 10 forms an endometriosis?
- A. There were several publications in the
- 12 early 2000s -- actually, it was probably in the
- 13 1990s -- that suggested that endometriomas were
- 14 clonal versus endometriosis not being clonal. But
- 15 there were very few, and they were never followed
- 16 up or confirmed. I have not done any personal
- 17 research on it. So...
- Q. To your knowledge, did Ms. Converse have
- 19 any risk factors for endo?
- A. The only risk factor for endometriosis is
- 21 transverse vaginal septum or imperforate hymen. To
- 22 the best of my knowledge, I don't think she had 23 either.
- 24 Q. Okay. Moving on to Judkins. I'm sorry,
- 25 let me back up. One more question on Converse.
 - Page 215
 - 1 Did you prepare any invoices --
 - A. I did not.
- 3 O. -- in Converse?
- 4 A. I have not.
- Q. Okay. Does your report contain all of
- 6 your opinions you intend to offer in this case?
- 7 A. Yes.
- Q. Are there any materials not listed on
- 9 your reference list that you're relying on for your
- 10 opinions in this matter?
- 11 A. No.
- 12 Q. And what did the Johnson & Johnson
- 13 lawyers ask you to do in this case?
- A. They asked me to evaluate the pathology
- 15 slides and determine a tumor, tumor type, tumor
- 16 stage, and whether there was any foreign material 16 that being high-grade serous carcinoma of the right
- 17 that could have contributed to the genesis of the
- 18 neoplasm.
- 19 Q. Incidentally, the -- in your report you
- 20 say the third thing they asked you to do was
- 21 provide your expert opinion on the hypothesized 21 physicians?
- 22 link between the peritoneal use of talc and the
- 23 development of ovarian cancer in general, and
- 24 specifically in this case. Your answer to that is
- 25 always no, right, in each of these reports?

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 - A. Can you repeat that? I'm sorry, I was a 2 little distracted.
 - 3 MR. HEGARTY: Object to the form.
 - 4 BY MR. DEARING:
 - 5 Q. Sure. You start every report by
 - 6 saying -- by identifying the scope of the report.
 - 7 And you state that you were asked to provide your
 - 8 expert opinion on, number one, diagnosis; number
 - 9 two, whether there is histologic evidence
 - 10 supporting internal exposure to talc-based body
 - 11 powder; and, three, the hypothesized link between
 - 12 perineal use of talc and the development of ovarian
 - 13 cancer in general, and specifically as it pertains
 - 14 to Ms. Judkins' ovarian cancer case.
 - 15 The answer to number three you know
 - 16 before you even write the first word of your
 - 17 report; right? I mean, it's always the same no
 - 18 matter what the slides show?
 - 19 MR. HEGARTY: Objection to form.
 - 20 THE WITNESS: That's because the slides
 - 21 always show an absence of tissue reaction to
 - 22 foreign particles in the ovaries or tubes.
 - 23 BY MR. DEARING:
 - 24 Q. And for that matter, the answer to number
 - 25 two is always the same as well, isn't it, that

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- 1 whether there's histologic evidence supporting
- 2 internal exposure to talc-based body powder. If
- 3 your opinion is talc can't get to the ovaries and
- 4 fallopian tube, your answer's always going to be
- 5 the same; right? You don't even have to look at
- A. Well, I'm perfectly willing to have my
- 8 mind changed. To do that I must see evidence,
- 9 though.
- 10 Q. Does Ms. Judkins' use of Johnson's baby
- 11 powder in any way influence your opinions in this
- 12 case?
- 13 A. It does not.
- 14 Q. In your opinion, was Ms. Judkins' cancer
- 15 properly diagnosed by her treating pathologist,
- 17 ovary?
- 18 A. Yes, it was correctly diagnosed.
- 19 Q. And do you disagree with any of the
- 20 statements or opinions of Ms. Judkins' treating

22

- A. Not that I can recall.
- 23 Q. In her brief clinical history section you
- 24 state that her family history is unremarkable
- 25 except for a paternal great aunt with breast cancer

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1 and a maternal uncle with kidney and bladder

- 2 cancer. Would you agree that both of those two
- 3 family cancers did not -- I'm sorry. Strike that.
- 4 Do you agree that neither of those
- 5 family cancers increased Ms. Judkins' risk of
- 6 ovarian cancer?
- 7 A. Agree.
- 8 Q. And she also had full panel genetic
- 9 testing; correct?
- 10 A. Yes.
- 11 Q. And do you agree that the genetic testing
- 12 did not reveal any germline mutations or other
- 13 findings known to increase a woman's risk of
- 14 ovarian cancer?
- 15 A. I agree.
- 16 Q. Do you agree that Ms. Judkins has no
- 17 recognized risk factors for high-grade serous
- 18 carcinoma of the ovary?
- 19 A. Other than age, no.
- Q. The question was do you agree, and you
- 21 said other than age, no.
- A. Oh, I'm sorry. You're right.
- Q. I know what you're trying to say.
- A. Let me set the record straight.
- Q. Did you recognize any risk factors for

- Page 220
 1 the sections, I can't tell whether there is direct

 - 2 contact, direct growth, or whether it was
 - 3 dissemination to the surface of the fallopian tube.
 - 4 Q. Okay. You go on to state that in the
 - 5 next sentence, the tumor exhibits areas of necrosis
 - 6 and aggregates of the foamy histiocytes. Those
 - 7 histiocytes, is that an inflammatory reaction to
 - 8 the dead cancer cells, the necrosis you're
 - 9 referring to?
 - 10 A. Yes.
 - 11 Q. And I should ask, the necrosis, is that
 - 12 necrosis of the tumor or healthy tissue?
 - 13 A. It is necrosis of the tumor.
 - 14 Q. I don't recall, do you know whether she
 - 15 had neoadjuvant chemotherapy?
 - 16 A. I don't believe she did.
 - 17 Q. Necrosis is something that occurs in
 - 18 tumors. That's just a normal process. Sometimes
 - 19 the cancer cells do just die at some point
 - 20 whether -- if they're not vascularized properly or
 - 21 something adequately?
 - A. There can be a number of reasons that
 - 23 tumor cells undergo necrosis. One of them is what
 - 24 you said, which is the theory of outgrew its blood
 - 25 supply. The second reason could be torsion of the

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- 1 high-grade serous ovarian cancer in Ms. Judkins'
- 2 medical records?
- 3 A. Only her age.
- 4 Q. I don't believe Mark would ever try to
- 5 twist that statement at trial, but it won't be Mark
- 6 at trial, so possibly.
- 7 You state in the first paragraph of
- 8 the examination of the pathology slide section the
- 9 slides revealed high-grade serous carcinoma arising
- 10 in the right ovary and involving the serosa of the
- 11 fallopian tube. Can you just describe what that
- 12 means?
- 13 A. Yes. As you look at it in your diagram,
- 14 the serosa of the fallopian tube is the outer layer
- 15 of the fallopian tube, or the outside of the
- 16 fallopian tube.
- 17 Q. Okay. When you say it involves that, are
- 18 there adhesions of the tumor?
- 19 A. There's a tumor growing on it.
- Q. Okay. Is that detached from the tumor
- 21 growing on the ovary, or is the tumor so big it's
- 22 touching both?
- A. It's hard to say from the sections. So
- 24 let's see if they describe it in the pathology
- 25 report. They did not describe it. So just from

- 1 ovary.
 - 2 Q. Okay.
 - 3 A. And ovarian tumors put the woman at
 - 4 risk -- at higher risk of ovarian torsion.
 - 5 Q. Okay. You can't tell by looking at
 - 6 slides whether that torsion existed in this case,
 - 7 can you?
 - 8 A. I would not be able to, no.
 - Q. But these aggregates of foamy
 - 10 histiocytes, that's an inflammatory reaction;
 - 11 right?
 - 12 A. It is a very specific type of
 - 13 inflammatory reaction, yes.
 - 14 Q. You go on to state that Ms. Judkins'
 - 15 tumor was an HGSC, high-grade serous carcinoma, of
 - 16 the usual type, and was not associated with
 - 17 granulomatous inflammation or a foreign body
 - 18 reaction. And I guess my question is, how do you
 - 19 know that?
 - A. Morphologically it's very, very easy to
 - 21 determine both granulomatous reactions --
 - 22 granulomatous inflammation, excuse me -- for
 - 23 foreign body reactions.
 - Q. But if that tumor was formed by or
 - 25 associated with an inflammatory foreign body

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- 1 reaction, wouldn't the evidence of that be subsumed
- 2 in the tumor?
- 3 A. Subsumed. You --
- 4 Q. Yeah. So the tumor is --
- 5 MR. HEGARTY: Objection. Go ahead.
- 6 THE WITNESS: Can you define subsumed?
- 7 BY MR. DEARING:
- 8 Q. So the tumor is new growth; right?
- 9 A. Yes.
- 10 Q. So if that new growth was instigated by
- 11 an inflammatory reaction, say a foreign body
- 12 reaction, it would grow up around it and evidence
- 13 of the carcinogenesis would be obliterated; right?
- 14 MR. HEGARTY: Objection to form.
- 15 THE WITNESS: No, I don't think the tumor
- 16 would destroy a foreign body reaction.
- 17 BY MR. DEARING:
- 18 Q. So in your opinion, if that tumor was
- 19 initiated by a foreign body reaction, you would be
- 20 able to locate the foreign body? I mean, you think
- 21 it's that obvious?
- 22 A. Sure, yes.
- Q. Okay. You also state that although
- 24 birefringent particles can be observed in
- 25 Ms. Judkins' histology slides under polarized

- 1 produce any. That because none have been created 2 yet?
- 3 A. You are correct.
- 4 Q. Do you know whether you retained a copy
- 5 of the chain of custody forms that traveled with
- 6 the slides that you reviewed for this case?
- 7 A. Very likely, but I neglected to bring it
- 8 to this deposition.
- 9 Q. Okay. We can move on to Gallardo.
- 10 Anybody need to take a break?
- 1 A. I'm good to go.
- 12 Q. To begin with, does your report contain
- 13 all of your opinions you intend to offer in this
- 14 case?
- 15 A. Yes, it does.
- 16 Q. Are there any materials not listed on
- 17 your reference list that you're relying on for your
- 18 opinions in this matter?
- 19 A. There are not.
- Q. And what did Johnson & Johnson's lawyers
- 21 ask you to do in this case?
- A. They asked me to evaluate the pathology
- 23 of Ms. Gallardo and to determine the type of cancer
- 24 that she had, and the stage, as well as to assess
- 25 whether there was any external particles that may

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- 1 light, these particles are not demonstrably within
- 2 macrophages or associated with a foreign body
- 3 reaction. When you say not demonstrably within
- 4 macrophages, does that mean you just -- you don't
- 5 see them within the macrophages?
- 6 A. Correct.
- 7 Q. Do you have an opinion as to what caused
- 8 Ms. Judkins' high-grade serous carcinoma of the
- 9 right ovary?
- 10 A. Yes, I believe it was a sporadic cancer.
- 11 Q. Did you make any new slides in
- 12 Ms. Judkins' case.
- 13 A. I did not.
- 14 Q. Did Johnson & Johnson's lawyers send you
- 15 Ms. Judkins' tissue blocks?
- 16 A. They did not.
- 17 Q. Did you request to see the blocks?
- 18 A. I did not.
- 19 Q. Do you intend to comment on any other
- 20 slides or other features of any other slides in
- 21 this case?
- A. Only those that are present in my report.
- Q. Prior to the deposition we asked that you
- 24 produce invoices in this case for your work done
- 25 for the Johnson & Johnson lawyers, and you did not

- 1 have contributed to the genesis of her neoplasm.
- 2 Q. Do you believe that Ms. Gallardo's cancer
- 3 was properly diagnosed by her treating physicians?
- 4 A. Yes.
- 5 Q. Do you disagree with any of the
- 6 statements or opinions of any of Ms. Gallardo's
- 7 treating physicians?
- 8 A. Not to the best of my recollection, no.
- 9 Q. Does the degree of usage of Johnson's
- 10 baby powder by Ms. Gallardo in any way impact your
- 11 opinions in this case?
- 12 A. It does not.
- 13 Q. Is it your opinion that Ms. Gallardo had
- 14 stage two endometrioid ovarian carcinoma?
- 15 A. Yes.
- 16 Q. With regard to her family history, you
- 17 state that her family history includes multiple
- 18 myeloma diagnosed in her father, leukemia in a
- 19 maternal half-brother and a maternal aunt, and
- 20 kidney cancer in a maternal uncle. Do you agree
- 21 that none of those family cancers contributed to
- 22 cause Ms. Gallardo's stage two endometrioid ovarian
- 23 cancer?
- 24 A. I agree.
- O. You're also aware that Ms. Gallardo

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1 underwent a full panel genetic testing?

- A. Yes.
- 3 Q. And do you agree that that testing did
- 4 not identify any pathogenic mutations?
- 5 A. I agree.
- 6 MR. HEGARTY: Objection to form.
- 7 BY MR. DEARING:
- Q. And do you agree that that panel testing
- 9 failed to show any genetic mutations found that are
- 10 known to increase a woman's risk of ovarian cancer?
- A. I agree.
- 12 Q. Let me ask that in a different way. Do
- 13 you agree that her panel testing showed that there
- 14 are no genetic mutations found that are known to
- 15 increase a woman's risk of ovarian cancer?
- A. I agree.
- 17 Q. And I should have mentioned this, but her
- 18 endometrioid adenocarcinoma was bilateral, in other
- 19 words, involved both ovaries; correct?
- 20 A. Yes.
- 21 Q. You state on page 5 at the top that as
- 22 with many endometrioid carcinomas, Ms. Gallardo's
- 23 endometrioid adenocarcinoma occurred in the
- 24 background of endometriosis best appreciated in
- 25 sections of her right ovary. But there are no

- 1 photographs in this report. Did you photograph
- 2 that background of endometriosis?
- 3 A. I did not.
- 4 Q. Is that something you actually observed
- 5 in her slides or something you're speculating
- 6 about?
- 7 A. No, I -- I observed it.
- Q. Any reason why you didn't photograph it
- 9 like you did in the other cases?
- A. I guess I didn't feel I needed it in this 10
- 11 instance. It wasn't -- it was not arising directly
- 12 from the focus of endometriosis. There was just 12 reports? And then you can tell me what the
- 13 the focus of endometriosis was present.
- Q. Well, do you think that her endometriosis 14
- 15 contributed to cause her endometrioid
- 16 adenocarcinoma?
- 17 A. Yes.
- Q. And do you agree that Ms. Gallardo's
- 19 pathologist didn't make mention of this tumor
- 20 occurring in the background of endometriosis?
- 21 A. (No answer given.)
- 22 Q. I'm going to go ahead and introduce
- 23 Exhibit 13, which is Ms. Gallardo's surgical
- 24 pathology report.
- 25 (Exhibit 13 marked for identification.)

Q. So I'm marking plaintiff's Exhibit 13,

- 2 which is the Gallardo pathology report. I think
- 3 we're looking at the same report. I don't have any
- 4 reason to think we're not, but I didn't see any
- 5 mention of endometriosis?
- A. I don't see it either. There are errors 6
- 7 in this report. I'm pretty sure it's in this one
- 8 as well. Oh. Oh, this is -- this is not nice. So
- 9 in this copy that I have, this format, there is a
- 10 microscopic description that contradicts the
- 11 diagnosis, but it is gone from this report.
- 12 Q. Well, that's tricky.
- 13 A. Yeah, isn't it? That --
- 14 Q. Let me see if I have another copy of that
- 15 report.

21

- 16 A. Yeah, I don't know how this -- how this
- 17 was printed, but it was -- it's clearly a
- 18 different -- is it a different format. It's
- 19 definitely formatted differently. And the
- 20 microscopic description differs between the two.
 - Q. Well, that's unfortunate.
- 22 A. They probably noticed it and amended the
- 23 report, but they should have mentioned that.
- 24 Q. Let me just see if I have another copy.
- 25 A. While you do that, I'm going to go to the

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1 bathroom. I apologize.

2 (Break taken.)

MR. DEARING: For the record, I'm marking

4 as plaintiff's Exhibit 14 a different copy of the

- 5 pathology report that Mr. Hegerty was kind enough
- 6 to share with me. And these two reports are
- 7 different. There's a different entry in one
- 8 section of it.
- 9 BY MR. DEARING:
- 10 Q. So Doctor, let me just get you to
- 11 explain, what is the difference in these two
- 13 significance is.
- A. The difference in the two reports is that
- 15 the microscopic description in the second copy, the
- 16 one that you marked, contains a comment saying
- 17 sections show high-grade serous carcinoma involving
- 18 both ovaries and present on the surface of one of
- 19 the ovaries. The right fallopian tube shows serous
- 20 tubal intraepithelial carcinoma with invasion.
- 21 This could be considered as a precursor lesion in
- 22 this neoplasm.
- 23 The report that you handed me says,
- 24 "Microscopic description and comment. Microscopic
- 25 examination substantiates the above diagnosis." I

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- 1 notice that the -- the report -- the person
- 2 responsible for the report, his name is Horacio
- 3 Maluf. The comment -- microscopic description and
- 4 comment -- was written by Reza Alaghehbandan.
- 5 Sorry.
- Q. Could this just be a mistake? 6
- 7 A. You want me to give you my best
- 8 hypothesis of what happened?
- Q. I would.
- 10 A. Yes. I believe Reza is a resident who
- 11 wrote the comment. And before the -- Dr. Maluf
- 12 signed off the report, and Dr. Maluf forgot to take
- 13 it out before signing it out.
- Q. Is it possible she's talking about a
- 15 different case entirely? Because she's calling it
- 16 high-grade serous carcinoma.
- 17 A. Yeah. Well, the Reza could be a
- 18 man-person.
- 19 Q. Oh, true. Okay. The person.
- 20 A. What's the date of execution of this
- 21 report?
- 22 MR. HEGARTY: Now you're looking at
- 23 Exhibit 13; correct?
- 24 BY MR. DEARING:
- Q. Well, so this one -- yeah, so this one is 25

- 1 Q. Because you didn't think it was
 - 2 necessary?
 - 3 A. Correct.
 - 4 Q. Don't you think it would be easier for us
 - 5 to evaluate your opinion if you took a picture of
 - 6 the endometriosis that you -- that this tumor is
 - 7 arising from?
 - 8 A. It might be useful for another
 - 9 pathologist to confirm that.
 - 10 Q. Right. Not me.
 - A. But that other pathologist should be
 - 12 perfectly capable of looking at a slide and finding
 - 13 it.

11

- 14 Q. Well, can you at least identify which
- 15 slide it is you made that observation in?
- A. Best appreciated in sections of her right 16
- 17 ovary.
- 18 Q. There's probably more than one slide of
- 19 the right ovary; right?
- 20 A. So it would be B18.
- 21 Q. Slide B18 shows the background of
- 22 endometriosis?
- 23 A. Correct.
- 24 O. And what does that mean that there's a
- 25 background of endometriosis, just that there's an

- 1 reported five days --
- A. Later.
- 3 Q. The one without the comment is reported
- 4 five days --
- A. Later.
- Q. -- later than the one with the comment.
- 7 So it was taken out.
- A. Yeah, it was taken out.
- 9 Q. So there was probably an error.
- A. Correct. It is an endometrioid
- 11 carcinoma. You asked me if I disagreed with
- 12 anything in the report, and I just noticed that,
- 13 and I go ipes.
- Q. To be clear, you observed no serous
- 15 features in these tumors?
- A. I observed no serous carcinomas. 16
- 17 Q. All right. That was interesting.
- 18 A. Sneaky.
- 19 Q. The question that led to all of that was
- 20 there's no evidence of endometriosis or no mention
- 21 of endometriosis in the pathology reports; correct?
- 22 A. Correct.
- 23 Q. And you observed it but didn't photograph
- 24 it?
- 25 A. Correct.

- Page 233 1 endometriosis present in the vicinity of the tumor?
- 2 A. In the genital tract, yes. And that
- 3 those associations between endometriosis and
- 4 endometrioid carcinomas and endometriosis and clear
- 5 cell carcinomas all use that -- that term in the
- 6 background of, meaning most of the time when a
- 7 tumor arises in an endometrioma, you can't see
- 8 endometrioma left in there anymore. It's overgrown
- 9 by tumor.
- 10 But in some instances it's -- like two
- 11 cases ago -- we can see normal endometrioma left.
- 12 But if there's endometriosis elsewhere in the
- 13 pelvis, the assumption is that the tumor arose in
- 14 one of those fossa.
- 15 Q. Well, you go on to identify a dozen or
- 16 more other organ sites in the last part of that
- 17 paragraph. I'm not going to read them all, but you
- 18 include the cervix, the uterus, the tubes. There
- 19 was no, no endometriosis in any of those organ
- 20 sites, was there?
- 21
- 22 Q. So the only endometriosis you found was
- 23 in her right ovary; correct?
- 24 A. Correct.
- 25 Q. So her right ovary, in your opinion, had

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1 evidence of endometriosis?

- 2 A. Yes.
- 3 Q. And it had an endometrioid adenocarcinoma
- 4 as well. The left ovary did not -- did not have
- 5 any evidence of endometriosis?
- 6 A. Correct.
- 7 Q. But the left ovary did have an
- 8 endometrioid adenocarcinoma; correct?
- 9 A. Correct.
- 10 Q. So is it your opinion that if you find
- 11 endometrioid adenocarcinoma, and you find
- 12 endometriosis in her gynecologic tissue, the
- 13 endometriosis must have caused the endometrioid
- 14 carcinoma?
- 15 A. The endometrioid carcinoma arose in a
- 16 focus of endometriosis.
- 17 Q. Okay. What does that mean? Does that
- 18 mean that the endometriosis caused it, or
- 19 contributed to cause it, or what?
- 20 A. It arose from it. So you don't -- you
- 21 don't have it normally endometriotic tissue in the
- 22 pelvis or the ovary. It's not -- normal woman
- 23 don't have that.
- 24 Q. Okay.
- 25 A. There are fossa in the endometriosis, in

- 1 A. I don't believe that they do.
- 2 Q. Okay. So --
- 3 A. Either endometriosis or endometrioma.
- 4 Q. Okay. So is it your opinion that any
- 5 time an endometrioid carcinoma of the ovary is
- 6 formed, it has to have derived from endometriotic
- 7 tissue, whether it's endometriosis or an
- 8 endometriotic cyst?
- A. That is my opinion.
- 10 Q. A hundred percent, all the time?
- 11 A. Yes
- 12 Q. Do you have any source for that opinion,
- 13 or is that just based on your experience?
- 14 A. There -- you mean a hundred percent of
- 15 them being --
- 16 Q. Yeah. I know there are studies that show
- 17 an association between endometriosis and
- 18 endometrioid carcinomas. I'm not aware of a source
- 19 that says that all endometrioid carcinomas are
- 20 formed from endometriotic tissue, whether it's --
 - A. Yeah, I -- that is such an obvious
- 22 deduction that I'm not sure anybody would have
- 23 bothered to publish it. It's just because tumors
- 24 arise from epithelium, whatever epithelium, right?
- 25 It has to arise in the epithelium that gives it its
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21

- 1 the pelvis or ovary, in women who have
- 2 endometriosis. Sorry, let me repeat that. There
- 3 are foci in the endometriotic tissue in women who
- 4 have endometriosis. If the tumor that arises in
- 5 the endometrioid, it had to arise from
- 6 endometriotic tissue. So that's why there's
- 7 that -- that association exists.
- 8 Q. Well, the right area -- sorry. The right
- 9 ovary and the left ovary are significantly
- 10 anatomically apart. So my question is, how do you
- 11 know that the endometrioid carcinoma of the left
- 12 ovary arose out of endometriosis when they're not
- 13 even near each other?
- 14 MR. HEGARTY: Objection, form.
- 15 BY MR. DEARING:
- 16 Q. In other words, there's no evidence of
- 17 endometriosis in the left ovary.
- 18 A. Correct. But -- but that ovary was
- 19 almost entirely replaced.
- Q. So you're saying it may have been there
- 21 at some point and we can't see it?
- A. Correct.
- Q. Okay. Can you estimate what percentage
- 24 of endometrioid carcinomas occur unrelated to
- 25 endometriosis?

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 1 histogenesis. So serous carcinomas arise from the
- 2 serous cells in the fallopian tube, whether it's in
- 3 the fallopian tube itself or whether the serous
- 4 cells get into the ovary. Endometrioid tumors have
- 5 to be -- have to arise in endometriotic tissue.
- 6 Q. Okay. So the term endometrioid isn't
- 7 just describing the morphology or what the cells
- 8 look like, it's actually describing the origin
- 9 cells?
- 10 A. Yes.
- 11 Q. Okay. On page 8 of your report where you
- 12 are discussing Dr. Godleski's findings --
- 13 A. Yes.
- Q. -- at the top you say, "The only foreign
- 15 particles photographed by Dr. Godleski that cannot
- 16 be dismissed as processing artifact are those
- 17 within macrophages of the right iliac lymph node,"
- 18 which is the same location we talked about earlier;
- 19 right?
- 20 A. Yes.
- Q. And you actually observed those particles
- 22 yourself in macrophages in the slides?
- 23 A. Yes.
- Q. And the right iliac lymph node drains
- 25 from the pelvis; right?

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- A. Or external genitalia and upper thigh as
- 2 well.

1

- 3 Q. Can you describe how -- Well, strike
- 4 that.
- 5 You go on to say that none of the
- 6 other birefringent material in figure two is
- 7 present within the cytoplasm of macrophages or any
- 8 other cell type. And none of this material is
- 9 associated with a foreign body reaction which is
- 10 consistent with simple postsurgical contaminant
- 11 introduced in the specimens when the tissues were
- 12 surgically removed from Ms. Gallardo and then
- 13 handled, grossed, and processed for histology
- 14 review.
- 15 Further, the foreign particles shown
- 16 in the bottom right panel of figure two are not
- 17 associated with chronic inflammation as claimed by
- 18 Dr. Godleski.
- 19 In your opinion, what is shown in
- 20 figure two that you're describing right there?
- 21 A. An aggregate of cells that I'm not sure
- 22 what they are from the photograph.
- 23 Q. Could they be macrophages?
- 24 A. They don't look like macrophages, no.
- 25 They look like either epithelial cells or

- 1 a macrophage or a lymphocyte.
- Q. But what determines whether the response
- 3 is a PMN or whether it's a macrophage?
- A. PMNs are -- have a nonspecific response
- 5 to -- usually to bacteria, but they could also be
- 6 present after tissue injury, whereas macrophages
- 7 are much more specific molecules that are attracted
- 8 by -- by signals from the -- from the surrounding
- 9 tissue.
- 10 Q. Do the PMNs appear to be associated with
- 11 those particles?
- 12 A. Yeah, they are clustered together with
- 13 these particles.
- 14 Q. Do you think the particles attracted the
- 15 PMNs?
- A. I doubt it. 16
- Q. Or are the PMNs responding to the 17
- 18 presence of the particles?
- 19 MR. HEGARTY: Objection to form.
- 20 THE WITNESS: I think their clustering is
- 21 coincidental, to tell you the truth.
- 22 BY MR. DEARING:
- Q. I guess anecdotally, if you have a
- 24 cluster of foreign particles such as in that
- 25 diagram, wouldn't that attract PMNs?

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- 1 lymphocytes.
- Q. And do they have birefringent particles
- 3 in them or associated with them?
- A. They're associated with them. I don't
- 5 think they're in them. There's several particles
- 6 that are clearly outside of any cytoplasm, just
- 7 lying on the tissue.
- Q. You say, "The photographed cells are
- 9 polymorphonuclear leukocytes."
- 10 A. Okay. So it's acute inflammatory cells.
- 11 I must have written that by looking at the
- 12 microscopic section rather than -- than the
- 13 photograph.
- 14 Q. Those are acute inflammatory cells?
- 15 A. Correct.
- Q. Can you describe what mechanism
- 17 distinguishes between just your normal inflammatory
- 18 reaction and an acute reaction? Is that because of
- 19 the volume or the number of cells?
- 20 A. No, it's the type of cell. So --
- 21 Q. Right.
- 22 A. -- a polymor --
- 23 Q. Go ahead. I'm sorry.
- 24 A. A polymorphonuclear leukocyte is a very
- 25 specific type of cell. It differs completely from

- Page 241 A. No. I mean -- no. So it would attract
- 2 macrophages if they were there while the tissue was 3 vital.
- 4 Q. So you think it's just coincidence that
- 5 the PMNs exist in that space and the particles just
- 6 landed on top of them --
- 7 A. Yeah. I mean --
- 8 Q. -- but nowhere else?
- A. Well, no, that's not true. They're
- 10 scattered --
- 11 O. There are a few others --
- 12 A. Yeah.
- 13 Q. -- but they're definitely gathered up on
- 14 top of it.
- 15 A. Yeah. And it may be that the PMNs are a
- 16 little stickier.
- Q. Okay. How do the PMNs differ in 17
- 18 appearance from macrophages?
- 19 A. PMNs have a lobulated nucleus, usually
- 20 three distinct lobules. The macrophage nucleus is
- 21 round and single.
- 22 Q. Okay. Did you identify any risk factors
- 23 for Ms. Gallardo that may have contributed to cause
- 24 her ovarian cancer?
- 25 A. Other than her age, no.

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- 1 Q. Did Johnson & Johnson's lawyers send you
- 2 any of Ms. Gallardo's tissue blocks?
- A. They did not.
- 4 Q. Did you ask to see any of her tissue
- 5 blocks?
- 6 A. I did not.
- 7 Q. Do you intend to comment on any other
- 8 slides other than B18 that you discussed
- 9 previously --
- 10 MR. HEGARTY: Objection to form.
- 11 BY MR. DEARING:
- 12 Q. -- during your testimony at trial.
- 13 A. Well, I intend to discuss all of the
- 14 slides in her case.
- Q. Did you take photos of any of the slides?
- 16 A. I did not.
- 17 Q. Have you produced any invoices in this
- 18 case?
- 19 A. I have not.
- 20 Q. And to your knowledge, did you retain any
- 21 of the chain of custody documents?
- A. Again, likely, but I didn't bring it to
- 23 the deposition by omission.
- Q. Okay. We're going to Ms. Bondurant.
- 25 First off, does this report contain all of your

- 1 carcinoma.
- Q. Is there a distinction?
- A. Some people believe that you can have
- 4 tumors with clear cell features that are not clear
- 5 cell carcinomas or pure clear cell carcinomas. In
- 6 this instance, all I had was one needle core
- 7 biopsy, and the entirety needle core was, in my
- 8 opinion, clear cell carcinoma.
- 9 Q. Okay.
- 10 A. To answer your second question, I did not
- 11 disagree with any of her clinical doctors.
- 12 Q. Okay. Near the bottom of page 4 you say,
- 13 "On 3/28/19, a CT-guided needle biopsy of a
- 14 possible liver mass reported metastatic high-grade
- 15 clear cell adenocarcinoma consistent with Mullerian
- 16 origin." Is that a metastasis from the ovarian
- 17 cancer?
- 18 A. Yes.
- 19 Q. Is that what that's from? On the next
- 20 page you describe her family -- her medical history
- 21 as significant for tubal ligation, hysterectomy for
- 22 fibroid uterus and endometriosis, and three
- 23 C-sections. In your opinion, did anything in that
- 24 medical history contribute to cause her clear cell
- 25 carcinoma?

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- 1 opinions that you intend to offer in this case?
- 2 A. It does.
- Q. Are there any materials not listed on
- 4 your reference list that you're relying on for your
- 5 opinions in this case?
- 6 A. I am not.
- 7 Q. And what did the Johnson & Johnson
- 8 lawyers ask you to do in this case?
- 9 A. They asked me to examine Ms. Bondurant's
- 10 pathology slides and determine what kind of tumor
- 11 she had, and what stage it was, and if there were
- 12 any foreign material that could have contributed to
- 13 her tumor.
- 14 Q. In your opinion, did Ms. Bondurant's
- 15 doctors properly diagnose her cancer?
- 16 A. Yes.
- 17 Q. Do you disagree with any of the
- 18 statements or opinions of Ms. Bondurant's treating
- 19 physicians?
- 20 A. May I modify my answer to that?
- 21 Q. Of course.
- A. They -- the doctors at Tulane, the
- 23 pathologists there, called it high-grade carcinoma
- 24 with clear cell features. I went a little bit
- 25 further than that and called it clear cell

- 1 A. Yes, her endometriosis.
- 2 Q. Do you believe that all clear cell
- 3 carcinomas are caused by endometriosis?
- 4 A. They're not caused by it. They arise
- 5 from it.
- 6 Q. Okay. So your opinion is that all
- 7 endometrioid ovarian carcinomas and all clear cell
- 8 ovarian carcinomas arise from endometriosis?
- 9 A. Endometriosis or endometrioma.
- 10 Q. Without exception?
- 11 A. In my mind, without exception.
- 12 Q. Her family history includes ovarian
- 13 cancer from of a maternal great aunt, breast cancer
- 14 of a mother and maternal aunt, and prostate or
- 15 pancreatic cancer from a maternal uncle,
- 16 non-Hodgkin's lymphoma from a brother, lymphoma of
- 17 a maternal grandmother, lung cancer from a brother
- 18 and other relatives, throat cancer from an uncle.
- 19 In your opinion, did any of those
- 20 family cancers contribute to cause her clear cell
- 21 carcinomas?
- A. Well, her history of -- of ovarian cancer
- 23 and maternal great aunt breast cancer and mother
- 24 and maternal aunts would seem to -- would increase
- 25 the risk that she would develop ovarian cancer.

62 (Pages 242 - 245)

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Q. Well --

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- 2 A. That's one first -- one first-degree and 3 two second-degree relatives.
- Q. Right. Do you know whether -- well,
- 5 first of all, you don't know the histology or the
- 6 subtype of ovarian cancer that her maternal great 7 aunt had, do you?
- A. I do not.
- O. Do you know whether if it was serous
- 10 carcinoma, which would make up a significant
- 11 percentage of the ovarian cancers, if her maternal 11
- 12 great aunt had the most common ovarian cancer,
- 14 cause her endometriosis in your opinion?
- MR. HEGARTY: Objection to form. 15
- 16 BY MR. DEARING:
- Q. Or put her at greater risk of
- 18 endometrioid carcinoma? Let me start over.
- A. Clear cell carcinomas.
- 20 Q. Let me start that all over. You can tell
- 21 it's the last one.
- 22. Is it true that we don't know what
- 23 type of ovarian cancer Ms. Bondurant's maternal 23
- 24 great aunt had?

1

25 A. That is correct. 1 carcinoma from that endometriosis?

- A. I -- family history doesn't specify a
- 3 mechanism. So it just basically says you're more
- 4 likely to get cancer.
- Q. Do you believe clear cell carcinomas are
- 6 influenced by hormones? Carcinomas of the ovary.
- A. They should not.
- 8 Q. Typically -- is it fair to say that
- 9 typically they are not?
- 10 A. Correct.
 - Q. And to be clear, none of those other
- 12 cancers mentioned in her family history, other than
- 13 serous carcinoma, would that have contributed to 13 her mother's and her maternal great aunt's, are
 - 14 likely to have contributed to her clear cell
 - 15 carcinomas; right?
 - 16 A. Correct.
 - 17 Q. Moving down to the next section where you
 - 18 examined the pathology slides, there was one slide
 - 19 available for review; correct?
 - 20 A. That is correct.
 - 21 Q. Did that one slide have any evidence of
 - 22 endometriosis in it?
 - A. No.
 - Q. So your opinion that Ms. Bondurant's
 - 25 clear cell carcinoma arose from endometriosis is

- Q. You agree that by far the most common
- 2 type of ovarian cancer is serous ovarian cancer?
- A. Agree as well.
- 4 Q. If she had -- the maternal great aunt had
- 5 serous ovarian cancer, would that have increased
- 6 Ms. Bondurant's risk of getting clear cell
- 7 carcinomas?
- 8 MR. HEGARTY: Objection, form.
- THE WITNESS: The -- the studies
- 10 associating family history to ovarian carcinoma
- 11 does not divide those carcinomas by cell type.
- 12 They just say increase the risk of ovarian cancer.
- 13 Again, because clear cell carcinomas constitute
- 14 such a small percentage of ovarian carcinomas, it
- 15 would be extremely difficult to ascertain whether
- 16 there is an received risk of those or not.
- 17 So the only statement that I can
- 18 make is that it puts Ms. Bondurant at an increased
- 19 risk for ovarian cancer. And that's as specific as
- 20 I can get.
- 21 BY MR. DEARING:
- Q. But it seems to me if all clear cell
- 23 carcinomas arise from endometriosis, how could a
- 24 family history of a great aunt's ovarian cancer
- 25 increase her risk of getting that clear cell

- Page 249 1 based solely on the fact that, in your opinion, all
- 2 clear cell carcinomas arise from endometriosis:
- 3 correct?
- 4 A. Well, it also derives from her own
- 5 personal history of having endometriosis.
- Q. Right. Okay. But you saw no evidence of
- 7 endometriosis in that slide that you studied?
- A. In that one needle core biopsy, no. By
- 9 the way, there were more than one slide, but they
- 10 were recuts that were stained for
- 11 immunohistochemistry. So --
- 12 Q. Do you know how many slides you reviewed
- 13 in all? I couldn't really tell --
- 14 A. Seven, including the H&E.
- 15 Q. Okay. You state that the morphologic and
- 16 immunohistochemical findings are diagnostic of a
- 17 clear cell carcinoma of Mullerian origin. What
- 18 does Mullerian origin mean?
- 19 A. The Mullerian tract is the embryologic
- 20 origin of the fallopian tubes, uterus, cervix, and
- 21 vagina.
- 22 Q. Embryologic? In other words --
- A. Yes. 23
- 24 Q. -- formed as an embryo?
- 25 A. Yeah. So how can I describe this? The

- 1 embryo starts forming structures in its abdomen,
- 2 okay? There are two major tubal systems, systems
- 3 of tubes. One of them is the Wolffian duct. The
- 4 Wolffian duct gives genesis to the kidneys,
- 5 ureters, bladder, and in the male -- both male and
- 6 female -- to the rete testes in the part of the
- 7 male, rete ovaria in the part of the female, as
- 8 well as the epididymis in the male, or the mucinous
- 9 breast in the female, and then the vas. All of
- 10 those arise from the Wolffian -- I'm sorry -- from
- 11 the Wolffian duct.
- 12 The Mullerian duct, which exists only
- 13 in the women, gives genesis to the fallopian tubes,
- 14 the uterus, the cervix, and the vagina. So when
- 15 you say Mullerian origin, it means it was either a
- 16 vaginal/cervical/uterine or fallopian tube
- 17 epithelium origin.
- 18 Q. So it was deriving from those organs.
- 19 A. The cell types of those organs.
- 20 Q. Right. But not in utero; right? I mean,
- 21 it was as a mature adult.
- 22 A. You're correct.
- 23 Q. You're just describing the organs from
- 24 which it derived.
- 25 A. Right. And the reason you use Mullerian

- Page 252 Q. So if a lady gets it in -- you know, in
 - 2 the '80s, she is likely to still have it in 2020?
 - A. Yes. It can -- it can become dormant,
 - 4 not cause symptoms. And part of the therapy for
 - 5 symptomatic endometriosis is to various -- they use
 - 6 various tactics, most of them hormonal -- either
 - 7 give the woman a lot of progesterone to stop the
 - 8 proliferation and attempt to put it into a dormant
 - 9 condition. There are some people who give chemical
 - 10 castration drugs to have the ovaries not secrete
 - 11 any estrogen. So -- so it can -- it can be put to
 - 12 sleep or become less symptomatic. And in some
 - 13 women, it stays dormant. In most women, it does
 - 14 not.
 - 15 Q. And by not being dormant, you mean that
 - 16 once the endometrial cells relocate to some organ
 - 17 where they shouldn't be, they then replicate where

 - 19 A. Again, they can in some -- in some people
 - 20 there's tiny foci. In other women, there's many
 - 21 large foci. It's really dependent on the case.
 - 22 There's a lot of variation.
 - 23 Q. Did you generate any invoices in the
 - 24 Bondurant case?
- 25 A. I did not yet, no.

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- 1 origin is to distinguish it from clear cell
- 2 carcinomas of the kidney.
- 3 Q. So even though it's of Mullerian origin,
- 4 how does the Mullerian origin relate to the
- 5 background of endometriosis?
- A. Endometriosis is Mullerian origin.
- 7 Q. As well.
- 8 A. As well.
- Q. Okay. If there were blocks available in
- 10 this case, you would not have looked at them, would
- 12 A. I would not have.
- 13 Q. Nor would you have asked for them?
- 14
- 15 Q. When you say that -- on page 7 you state
- 16 that this clear cell carcinoma arose within the
- 17 background of preexisting endometriosis. That's
- 18 based solely on the medical history that she had
- 19 endometriosis in the '80s, and then the fact of
- 20 your opinion that all clear cells arise from
- 21 endometriosis?
- 22 A. Correct.
- Q. Okay. Endometriosis does resolve
- 24 sometimes, doesn't it?
- 25 A. Almost never.

Page 253 Q. And do you know whether you retained a

- 2 copy of the chain of custody for the slides?
- A. Almost without question. I just 4 neglected to bring it to this deposition.
- MR. DEARING: All right. We can take
- 6 another break, and then I'll just look at my notes
- 7 and see if I forgot anything.
- 8 (Break taken.)
- 9 MR. DEARING: I don't have any other
- 10 questions.

EXAMINATION

- 12 BY MR. HEGARTY:
- 13 Q. Good afternoon, Dr. Felix.
- 14 A. Good afternoon.
- 15 Q. I have some follow-up areas that will
- 16 track Mr. Dearing's examination of you over the
- 17 last several hours.
- 18 You were asked about whether, in your
- 19 current practice, you meet with patients to discuss
- 20 your review and analysis of their tissue or their
- 21 cytology. But do you -- and you mentioned that you
- 22 typically do not meet with the patients, or rarely
- 23 have met with the patients that you've -- since
- 24 you've been at the Medical College of Wisconsin; is
- 25 that correct?

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A. Correct, yes.

1

- Q. But with regard to their treating
- 3 physicians, do you regularly interact with the
- 4 doctors who are treating the patients for their
- 5 ovarian and other gynecologic cancer with respect
- 6 to your review and analysis of their tissue or 7 cytology?
- A. Yes, almost on a daily basis.
- Q. Can you describe for us just briefly how
- 10 those interactions occur, or what transpires?
 - A. They can occur -- a law went into effect
- 12 that the minute you enter a medical record, it must
- 13 be accessible to the patient. Patients have
- 14 software called MyChart. So every time that
- 15 there's cancer, and I look into the provider and
- 16 it's not an oncologist where I know that the
- 17 person's expecting a cancer diagnosis if they went
- 18 to an oncologist -- but for every general gyn will
- 19 get a phone call from me to discuss the case. And
- 20 it usually involves a little education, because
- 21 general ob/gyns are not very familiar with
- 22 malignancies.
- So that's the number -- most common
- 24 interaction that I have. And that occurs almost on
- 25 a daily basis. Then I discuss cases at the time of
- - Page 255
- 1 tumor board. And -- and in those tumor boards I
- 2 very frequently will -- will make observations that
- 3 aren't -- my observation's intended to make the
- 4 clinician do something that they weren't planning
- 5 on doing. So I interact a lot with them.
- Q. Can you give us an example of where your
- 7 comments at a tumor board may lead the clinician to
- 8 do something that they weren't planning on doing?
- A. Yes. So the pathology report, the last
- 10 one that I remember, it was squamous cell
- 11 carcinoma. Maximum depth of invasion point was one
- 12 millimeter. But then it was present at the margin.
- And when they were discussing the case
- 14 they said, oh, it's one millimeter. We can just do
- 15 a simple hysterectomy. Oh, no, no, no, no, no.
- 16 It's one millimeter, but it could be much, much
- 17 deeper because it's at the margin. So basically I
- 18 went -- I basically asked them, to be completely
- 19 safe and not do a cut-through hysterectomy, you
- 20 should probably do a cold biopsy. So I
- 21 strong-armed them into doing a cold biopsy.
- O. You indicated earlier in your testimony
- 23 that as a general rule you do not use polarized
- 24 light microscopy when you're looking at a tissue
- 25 removed from a patient that potentially has ovarian

- 1 cancer and making that diagnosis.
 - When, over the course of your career,
 - 3 when and in what circumstances do you use polarized
 - 4 light microscopy?
 - A. I use it every time I have granulomatous
 - 6 inflammation or an unusual grouping of macrophages.
 - 7 In both of those situations, I will polarize the
 - 8 tissue.
 - Q. You indicated that you're not currently
 - 10 working on any publications that discuss ovarian
 - 11 cancer, but what are you doing on a weekly basis
 - 12 with regard to reviewing and diagnosing ovarian
 - 13 cancer?
 - 14 A. Currently I'm the only gyn pathologist at
 - 15 MCW, so I see every ovarian cancer that comes out.
 - 16 I see actually all of the gyn pathology samples
 - 17 that come out of the ORs, or clinics. So I'm
 - 18 getting help, thank goodness. I'm getting two
 - 19 people who are fellowship trained in gyn. So that
 - 20 will provide some relief. But I expect one of
 - 21 them, at least, to show me everything.
 - 22 Q. Approximately how many new ovarian cancer
 - 23 cases do you diagnose on a weekly basis?
 - 24 A. It varies from week to week, but I would
 - 25 say that an average of two to three a week.

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- Q. And with regard to those two to three a
- 2 week over the course of the month, which would add
- 3 up to be maybe twelve, are some of those the type
- 4 of cancer we've been talking about today, serous
- 5 endometrioid and clear cell?
- A. Yeah, most of them are serous. We do get
- 7 a fair amount of clear cell in Wisconsin for some
- 8 unusual reason.
- Q. You were asked by Mr. Dearing, counsel
- 10 for the plaintiffs in these cases, about the known
- 11 causes of ovarian cancer. And you talked about
- 12 gene mutations, and then later on you started
- 13 discussing with regard to the individual patients'
- 14 endometriosis. Is endometriosis a known cause of
- 15 certain types of ovarian cancer?
- 16 A. It is not the cause of ovarian cancer.
- 17 It is the tissue of origin of ovarian cancer.
- 18 Q. That may be the better way to put it.
- 19 When you talked to us earlier about clear cell and
- 20 endometriotic endometrioid carcinomas arising out
- 21 of endometriosis or an endometriotic cyst; is that
- 22 correct?
- 23 A. That's correct, yes.
- 24 Q. In one instance you showed us that, but
- 25 is this arising out of a -- a trans --

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- A. Transition?
- 2 Q. -- transition of endometriosis or of
- 3 endometriotic cyst to either clear cell or
- 4 endometrioid carcinoma?
- 5 A. Correct.

1

- 6 Q. Also cancer of the ovary, as we talked
- 7 about with regard to Ms. Balderrama, can be a
- 8 metastasis from uterine cancer; correct?
- 9 A. Correct.
- 10 Q. And with regard to these origins of
- 11 ovarian cancer, you talked about those, including 11 cancer does not develop from such a response;
- 12 gene mutations in your reports; correct?
- 13 A. Yes.
- 14 Q. You were asked some questions about
- 15 reactive oxygen species. With regard to reactive 15
- 16 oxygen species, are those created by the body in
- 17 response to exercise, for example?
- A. You can -- you can get reactive oxygen
- 19 species because of exercise, yes.
- 20 Q. I guess put it another way: Reactive
- 21 oxygen species are a normal part of human
- 22 physiology, and the body then deals with those
- 23 reactive oxygen species -- let me start over again.23
- Reactive oxygen species are a normal
- 25 part of human physiology; correct?
- Page 259

A. Correct.

1

- Q. You were asked about whether you'll offer
- 3 opinions regarding the epidemiologic literature as
- 4 it relates to talcum powder use and ovarian cancer.
- 5 To the extent that you would offer such opinions, 6 those are set out in your expert reports for the
- 7 cases we talked about today; correct?
- A. Correct.
- Q. You were asked about the type of
- 10 inflammatory response that foreign particles,
- 11 including talc, can cause in tissue. And those
- 12 are, as you identified, granulomatous for foreign
- 13 body response. Recall testifying to that?
- A. Yes. 14
- 15 Q. You were also asked about whether you had
- 16 reached any conclusions prior to being contacted by
- 17 Johnson & Johnson's counsel with regard to any
- 18 relationship between talc and ovarian cancer.
- 19 Certainly prior to being contacted by counsel for
- 20 Johnson & Johnson you were aware of the process we 20 almost a certainty.
- 21 just talked about of the body forming a -- or
- 22 having a foreign body or granulomatous response to
- 23 particles in tissue; correct?
- 24 A. Yes.
- 25 MR. DEARING: Object to form. Leading.

1 BY MR. HEGARTY:

2 Q. Were you also aware that such a response

3 does not cause any form of cancer?

- 4 MR. DEARING: Objection, form.
 - THE WITNESS: Not to my knowledge.

6 BY MR. HEGARTY:

- Q. So prior to being contacted by counsel 7
- 8 for Johnson & Johnson, it was your belief and
- 9 understanding that granulomas and foreign body
- 10 responses don't increase the risk of cancer or
- 12 correct?

5

- 13 MR. DEARING: Objection to form.
- 14 Leading.
- THE WITNESS: Correct.

16 BY MR. HEGARTY:

- 17 Q. And that your opinions in these cases
- 18 that talcum powder use does not cause ovarian
- 19 cancer are based on all of the authorities you cite
- 20 in your reports, which include the epidemiologic
- 21 studies, the cell studies and animal studies; is
- 22 that correct?
 - A. Yes.
- 24 Q. You were asked about a type of long-term
- 25 destructive inflammation that has been linked to

- 1 certain types of cancer. Can you describe for us
- 2 what that long-term destructive inflammation looks
- 3 like?
- 4 A. Yes. So in that long-term inflammation
- 5 you get constant tissue destruction and constant
- 6 tissue regeneration. And it is that regeneration
- 7 that prompts or makes mutations more likely.
- 8 Q. And is that constant destruction and
- 9 regeneration visible under the microscope?
- 10 A. It's very easily visible.
- 11 Q. And what cancers are associated with
- 12 that kind of destruction that happens from
- 13 long-term -- certain types of long-term
- 14 inflammation?
- 15 A. The best known are colon cancers arising
- 16 in ulcerative colitis, where the inflammatory
- 17 response constantly destroys the colonic mucosa.
- 18 And eventually I think the risk of developing colon
- 19 cancer up to age 60 is, like, 95 percent. So
- Q. Okay. And in the pathology slides you
- 22 look at on a daily basis, are you looking for that
- 23 and other types of inflammation, including that
- 24 could be characterized as -- as a foreign body 25 response or a granulomatous reaction?

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- 1 A. Yes. Again, the reason for that is
- 2 granulomas can be foreign body granulomas, but they
- 3 can also be infectious granulomas. And it's very
- 4 important to identify the infectious ones.
- 5 Q. You were asked some questions by
- 6 Mr. Dearing about whether you had seen reports of
- 7 asbestos in talcum powder. Do you recall those
- 8 questions?
- 9 A. Yes.
- 10 Q. I believe you had indicated, in response
- 11 to at least one of those -- one of the questions in
- 12 this line of questions, that talcum powder probably
- 13 did contain some level of asbestos. You were not
- 14 talking about Johnson's baby powder; correct?
- 15 MR. DEARING: Objection, form.
- 16 THE WITNESS: I was not talking about any
- 17 specific brand of talcum powder.
- 18 BY MR. HEGARTY:
- 19 Q. You have never seen reports of Johnson's
- 20 baby powder containing any levels of asbestos;
- 21 correct?
- 22 MR. DEARING: Objection, form.
- 23 THE WITNESS: I have -- I don't recollect
- 24 ever seeing a report saying that Johnson's product,
- 25 Johnson & Johnson baby powder, had asbestos.
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- 1 BY MR. HEGARTY:
- 2 Q. And it's not your opinion in these cases
- 3 that Johnson's baby powder has ever contained any
- 4 amount of asbestos; correct?
- 5 MR. DEARING: Objection, form.
- 6 THE WITNESS: It is not my opinion.
- 7 BY MR. HEGARTY:
- 8 Q. In fact, when you were talking about
- 9 reports of asbestos in talc, you made specific
- 10 reference to the IARC monograph talking about -- or
- 11 the IARC monographs you had read; correct?
- 12 A. Correct.
- 13 Q. And in those IARC monographs, they don't
- 14 specifically refer to the source of the talc that
- 15 they're talking about; correct?
- 16 A. That is correct as well.
- 17 Q. When you were talking about the asbestos
- 18 in talc, you were talking about over the course of
- 19 the -- the use of talc at whatever -- whatever
- 20 standards that -- whether it's industrial or other
- 21 standards -- that you have seen reports and perhaps
- 22 did believe as to certain of those reports, that
- 23 some types of talc over the years have contained
- 24 some amounts of asbestos?
- A. Correct.

- 1 Q. You were asked about the anatomical
 - 2 descriptions of the reproductive tract shown in
 - 3 Exhibits 3 and 4. Do we have Exhibits 3 and 4
 - 4 there? Now, with regard to those anatomical
 - 5 descriptions in those exhibits --
 - A. This is 1 and 2.
 - 7 Q. I'm sorry, 1 and 2. You were asked about
 - 8 the anatomical diagrams shown in Exhibit 1 and 2.
 - 9 Do each of those anatomical diagrams show a vagina
 - 10 that's open like an open tube?
 - 11 A. Yes.

14

- 12 Q. Is that a proper anatomical description
- 13 of what the vagina looks like?
 - A. It is not.
- 15 Q. Okay. What does the vagina look like?
- 16 A. The vagina is a potential space. So the
- 17 walls of the vagina touch each other.
- 8 Q. The anatomical description marked as
- 19 Exhibit 1 and 2 also show an open uterine cavity,
- 20 and also show an open fallopian tube. Is that what
- 21 they appear in real life?
- 22 A. No. The endometrium touches -- the
- 23 anterior endometrium touches the posterior
- 24 endometrium. So again, it's a potential space.
- Q. With regard to the fallopian tube, it's
- 263
 - 1 not a clear tube like a straw; correct?
 - 2 A. Correct. It's full of fimbriae -- plica,
 - 3 which is the mucosa of the fallopian tube.
 - Q. You were asked about Exhibit Number 3,
 - 5 which is one of the McDonald studies.
 - 6 A. Yes.
 - 7 Q. If you could find Exhibit Number 3 there.
 - 8 I have just a couple of follow-up questions.
 - 9 With regard to Exhibit Number 3, the
 - 10 McDonald study, is Dr. Godleski and his co-authors
 - 11 doing the same thing -- reporting on the same thing
 - 12 in this study that Dr. Godleski reported on in a
 - 13 number of the cases we talked about today?
 - 14 MR. DEARING: Objection, form.
 - 15 THE WITNESS: I'm sorry, can you repeat
 - 16 that question?
 - 17 BY MR. HEGARTY:
 - 18 Q. Sure. Is what Dr. Godleski and his
 - 19 co-authors are doing in this study essentially the
 - 20 same thing that Dr. Godleski has done in his
 - 21 reports for a number of the cases we talked about
 - 22 today?
 - 23 A. Yes.
 - 24 MR. DEARING: Objection, form.
 - 25 BY MR. HEGARTY:

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- 1 Q. In other words, did he essentially apply 2 the same methodologies in this McDonald study as he
- 3 applied in the reports that we talked about today?
- 4 A. That is correct.
- Q. And is it your understanding that in the
- 6 McDonald study, he reported on five patients who
- 7 are also litigation plaintiffs in cases involving
- 8 talc and ovarian cancer?
- 9 MR. DEARING: Objection, form.
- THE WITNESS: I've been informed of that,
- 11 yes.
- 12 BY MR. HEGARTY:
- 13 Q. As in his reports, Dr. Godleski and the
- 14 co-authors don't show any particles
- 15 identified -- don't prove that any particles -- let
- 16 me start over again.
- With regard to Dr. Godleski's and his
- 18 co-authors in the McDonald paper, they do not show
- 19 that any of the particles that they identified by
- 20 PLM are talc; correct?
- 21 A. Correct.
- Q. That's also what -- that's also the same
- 23 thing that Dr. Godleski says in the cases we talked
- 24 about today, that the -- that he cannot identify
- 25 the particles he reports on as being birefringent
 - Page 267
- 1 by PRM talc. You understand that?
- 2 A. Yes.
- 3 Q. And with regard to your response to the
- 4 McDonald study, does that -- does your response
- 5 track your response to what Dr. Godleski has done
- 6 in all the reports we talked about today?
- 7 MR. DEARING: Objection, form.
- 8 BY MR. HEGARTY:
- 9 Q. Does that make sense?
- 10 A. Yes.
- 11 Q. In the McDonald study, did Dr. Godleski
- 12 or his co-authors report on any foreign body
- 13 response or granulomatous to any particles?
- 14 A. The only foreign body response would be
- 15 phagocytosis of particles by macrophages.
- 16 Q. Did he and his authors report any
- 17 granulomatous or foreign body giant cells?
- 18 A. They did not.
- 19 Q. And with regard to the particles that you
- 20 identified as being in macrophages in the cases we
- 21 talked about today, those particles cannot be
- 22 identified as talc; correct?
- A. Correct.
- Q. You were also asked about Dr. Godleski's
- 25 plus or minus five percent factor in identifying

- 1 talc in tissue. Have you seen that plus or minus
 - 2 five percent variance used by any other author in
 - 3 any other published, peer-reviewed publication?
 - 4 A. Not that I'm aware of, no.
 - Q. You were asked about whether you would
 - 6 have opinions about asbestos and whether it can
 - 7 cause ovarian cancer, and you provided those
 - 8 opinions to Mr. Dearing. If you pull out just one
 - 9 of your reports -- it can be the Carl report.
 - 10 A. Okay.
 - 11 Q. If you turn over to page 5. In footnote
 - 12 two, you specifically reference a couple of
 - 13 authorities that you rely upon, among others, for
 - 14 your opinion that asbestos exposure does not cause
 - 15 ovarian cancer. Those authorities are particularly
 - 16 the Reid 2011 paper and the Slomovitz 2020 paper?
 - 17 A. Correct.
 - 18 Q. You were asked about your lab and the
 - 19 extent of any asbestos in that lab. And you talked
 - 20 about the potential for asbestos in your lab.
 - 21 Are you able to say that the
 - 22 laboratories that process the tissues that we've
 - 23 talked about here today have the same, perhaps,
 - 24 limitation of asbestos as your lab does here?
 - 25 A. Yes. Asbestos is pretty much everywhere.
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 - Q. But can you -- I know you can talk about
 - 2 your -- the asbestos potential for your lab here in
 - 3 Wisconsin, but can you talk about the asbestos
 - 4 potential in the labs of the -- of the hospitals
 - 5 that processed the tissues that we've been talking
 - 6 about here today?
 - 7 A. I can.
 - 8 Q. Have you -- have you been in each of
 - 9 those labs?
 - 10 A. I have not.
 - 11 Q. So are you able to comment about those
 - 12 labs as you're able to comment here about your lab?
 - 13 A. Yes. In general, all laboratories suffer
 - 14 from the same condition. Construction will
 - 15 inevitably leave trace asbestos fibers behind.
 - 16 Q. And some labs may have more asbestos
 - 17 fibers than others; correct?
 - 18 A. They may, uh-huh.
 - 19 Q. It can depend on the age of the
 - 20 laboratory; correct?
 - 21 A. Yes.
 - Q. It can depend on the level of
 - 23 construction that has gone on in and around the
 - 24 hospital complex where the lab is; correct?
 - 25 A. Correct.

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- 1 Q. You were asked about whether you were
- $2\,$ challenging Dr. Godleski's finding of talc by SEM
- 3 and EDX, that is, are you saying that he
- 4 misidentified the particles as talc. But are
- 5 you -- but are you challenging in these cases his
- 6 conclusions that whatever he has seen came from the
- 7 patient's use of Johnson's baby powder?
- 8 MR. DEARING: Objection, form.
- 9 THE WITNESS: Can you repeat that --
- 10 rephrase it?
- 11 BY MR. HEGARTY:
- 12 Q. Sure. Do you remember being asked about
- 13 whether you're taking issue with Dr. Godleski's
- 14 finding of talc in tissue, that is, saying that he
- 15 misidentified the particles as talc. Do you
- 16 remember being asked those questions?
- 17 A. Yes.
- 18 Q. But are you challenging, though,
- 19 Dr. Godleski's conclusions from those findings that
- 20 the particles he has seen came from the patient's
- 21 use of Johnson's baby powder prior to their
- 22 surgery?
- A. I am challenging that, yes.
- Q. And as far as the particles that
- 25 Dr. Godleski did detect by SEM EDX, whether they're 25

- 2 1 Q. That would include any patient's
 - 2 description of their baby powder use; correct?
 - A. Yes, it -- I was asked whether it
 - 4 mattered to my opinion, and I said no.
 - Q. And why does it not -- why does the
 - 6 specifics of each of the patient's use of Johnson's
 - 7 baby powder not matter to your opinions?
 - A. Because I don't find talcum powder
 - 9 associated with a foreign body reaction in any of
 - 10 them. So it doesn't matter to me whether they used
 - 11 a little or a lot. To me, nothing got up.
 - 12 Q. You had mentioned that particles greater
 - 13 than five microns or greater will cause a
 - 14 granulomatous reaction; is that correct?
 - 15 A. Correct.
 - 16 Q. And in fact in some of the cases we
 - 17 talked about, Dr. Godleski in his images showed
 - 18 particles that sometimes were well in excess of
 - 19 five microns?
 - 20 A. Correct.
 - Q. And in any of those cases were -- was
 - 22 there a granulomatous reaction?
 - 23 A. No.

24

- Q. What does that tell you?
- A. It tells me that that particle was not

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- 1 talc or otherwise, in your opinion, where did those
- 2 particles come from?
- 3 A. They likely came from processing.
- 4 Q. And in particular, as far as likely
- 5 coming from processing, your reports say that that
- 6 processing includes the handling, grossing and
- 7 the -- and preparing the slides using molten
- 8 paraffin wax; correct?
- 9 A. Correct.
- 10 Q. You were asked, as we talked about each
- 11 of the plaintiff's cases today, what you were asked
- 12 to do by Johnson & Johnson's counsel. And in each
- 13 case does your report set out on the very first
- 14 paragraph what you were asked to do?
- 15 A. Yes.
- 16 Q. And then does the report that follows
- 17 flow from what you were asked to do?
- 18 A. Yes.
- 19 Q. You were asked in each of these -- as to
- 20 each of the cases whether the plaintiff's use of
- 21 Johnson's baby powder was necessary for your
- 22 opinions in this case. In each of the -- in each
- 23 case we talked about here today, did you read the
- 24 plaintiff's deposition testimony?
- 25 A. Yes, in most of them.

1 there while the organ was vital.

- 2 Q. You were asked about the invoices in
- 3 Exhibit Number 4. Were some of the items that you
- 4 invoiced in Exhibit Number 4 your expenses?
- 5 A. Yes.
- 6 Q. Is that simply paying you back for
- 7 expenses that you incurred?
- 8 A. Yes.
- 9 Q. As to Ms. Balderrama, you were asked
- 10 about the basis for your conclusion that
- 11 her -- that the carcinoma found in her ovary was a
- 12 metastasis from the endometrium. Do you recall
- 13 being asked about that?
- 14 A. Yes.
- 15 Q. Do those bases include her clinical
- 16 history of having complex hydroplasia? And feel
- 17 free to look at your report.
- 18 A. No, I'm very aware of that. But yes, I
- 19 mean, meaning that -- that her endometrial cancer
- 20 started in her uterus, yes.
- Q. And is having a clinical history of
- 22 complex hyperplasia consistent with her ultimately
- 23 developing endometrial carcinoma?
- 24 A. Yes, complex hyperplasia with atypia is
- 25 the precursor lesion to endometrial cancer.

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- 1 Q. Do you also base your opinions that
- 2 Ms. Balderrama's ovarian tumor was a metastasis
- 3 from her endometrial tumor on the medical
- 4 literature that discusses simultaneous endometrial
- 5 and ovarian tumors?
- 6 A. Yes.
- 7 O. And does that include the medical
- 8 literature that has looked at the molecular genetic
- 9 data? In particular you make reference in your
- 10 report about that in the last ten years, molecular
- 11 genetic damage has accumulated to support the
- 12 current understanding that the vast majority of
- 13 these synchronous primary tumors are clonal in
- 14 nature and represent metastatic endometrial cancer.
- 15 You cite Verrick, among other authorities.
- 16 Are you also relying on those
- 17 authorities for your opinions as to Ms. Balderrama?
- 18 A. Yes.
- 19 Q. You were asked some questions about the
- 20 2020 O'Brien study. Do you recall being asked
- 21 about that study?
- 22 A. Yes.
- Q. In particular you were asked about the
- 24 sister study part of O'Brien 2020. Do you recall
- 25 that?

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- 1 A. Yes.
- 2 Q. Does O'Brien 2020 also include as
- 3 its -- its data data from the women's health
- 4 initiative and the nurses' health study?
- 5 A. It does.
- 6 Q. So does O'Brien -- do the inclusions from
- 7 the -- by the O'Brien authors include the sister
- 8 study -- or stem from their review of the sister
- 9 study, women's health study, and women's health
- 10 initiative data?
- 11 A. Correct.
- 12 Q. You were also asked questions as to each
- 13 plaintiff we talked about today as to the cause of
- 14 that plaintiff's cancer. Do you recall those
- 15 questions?
- 16 A. Yes.
- 17 Q. And does your report -- or do your
- 18 reports in these cases set out your causation
- 19 opinions?
- 20 A. Yes.
- 21 Q. And is one of those opinions that talc
- 22 use did not play a role in the development of each
- 23 plaintiff's ovarian cancer?
- 24 A. Yes.
- Q. And where indicated in your reports, was

- Page 276
- 2 ask it a different way.
- Where indicated in your reports in
- 4 those patients that had clear cell endometrioid

1 the -- the diagnosis of endometriosis -- or let me

- 5 carcinoma, did those cancers arise out of
- 6 endometriosis in each case?
- 7 A. Yes.
- 8 Q. And is it your opinion in each case that
- 9 the etiology of the endometrioid and clear cell
- 10 carcinomas was endometriosis?
- 11 A. Yes.
- 12 Q. And with regard to what you were asked to
- 13 do in this case, were you asked to review all the
- 14 medical records and comment on or provide testimony
- 15 about all of the plaintiffs' medical conditions and
- 16 risk factors?
- 17 A. I -- I mean, I did it. I tried to do it.
- 18 Q. But were you specifically asked to take
- 19 an in-depth look at all the risk factors of each
- 20 plaintiff, look at all the medical records, and
- 21 comment on each potential risk factor?
- 22 A. No.
- Q. So to the extent that a plaintiff in
- 24 these cases has a genetic mutation or other
- 25 recognized risk factor that should be considered in
 - Page 277
- 1 determining the etiology of that plaintiff's
 - 2 cancer, you were not asked to consider and provide
 - 3 testimony about such factors -- such risk factors
 - 4 beyond what's in your report; correct?
 - 5 MR. DEARING: Objection, form. Leading.
 - 6 THE WITNESS: Correct.
 - 7 BY MR. HEGARTY:
 - 8 Q. And with regard to the variants of
 - 9 unknown significance that we talked about in some
 - 10 of the reports, does that mean that the data is
 - 11 not -- is just not sufficient yet to determine
 - 12 whether those variants are associated with an
 - 13 increased risk of ovarian cancer?
 - 14 A. That is correct. Usually it means
 - 15 there's insufficient data.
 - 16 Q. And do any of the tests that we talked
 - 17 about here today, that is the genetic tests, rule
 - 18 out that the patient had a genetic mutation that,
 - 19 whether known or unknown, that could be related to
 - 20 their developing ovarian cancer?
 - A. It does not rule it out completely, no.
 - MR. HEGARTY: Let's go off the record.
 - 23 Give me about five minutes.
 - 24 (Break taken.)
 - MR. HEGARTY: Those are all the questions

	Page 278		Page 280
	I have for you, Dr. Felix. Thank you.	1	DEPOSITION ERRATA SHEET
2	EXAMINATION	2	
3	BY MR. DEARING:	3	DECLARATION UNDER PENALTY OF PERJURY
4	Q. I just have one. You mentioned that when	4	I declare under penalty of perjury
5	you observed granulomatous inflammation in slides,	5	that I have read the entire transcript of
6	that's when you decide to polarize them. Why do	6	my deposition taken in the captioned matter
7	you polarize them?	7	or the same has been read to me, and
8	A. Because if it's a foreign particle, I	8	the same is true and accurate, save and
9	don't have to do infectious disease stains.	9	except for changes and/or corrections, if
10	Q. So if it polarizes, that tells you it's a	10	any, as indicated by me on the DEPOSITION
11	foreign particle?	11	ERRATA SHEET attached, with the understanding
12	A. It's a foreign body granuloma, yes.	12	that I offer these changes as if still under
13		13	oath.
14	-	14	Signed on the day of
15		15	, 2024.
16		16	
17		17	
18	A. Correct. If they they usually will be	18	Juan Felix, MD
	visible by H&E, the ones that are not refringent.	19	Judii I Clix, IVID
20	•	20	
	refringent, then I'll get the stain.	21	
21 22	•		
23	· ·	22	
	ř	23	
24	9	24	
25	(Deposition concluded at 5:12 p.m.)	25	
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1	STATE OF WISCONSIN)		
) ss.		
2	COUNTY OF MILWAUKEE)		
3 4	I, ANITA KORNBURGER, Registered Professional Reporter and Notary Public in and		
5	for the State of Wisconsin, do hereby certify		
6	that the preceding deposition was recorded by		
7	me and reduced to writing under my personal		
8	direction.		
9	*		
10	· · · · · · · · · · · · · · · · · · ·		
11	Wisconsin, on June 22, 2024, commencing at 9:08 a.m. and concluding at 5:12 p.m.		
12 13			
14	· · · · · · · · · · · · · · · · · · ·		
15			
16	1 2		
17	· ·		
18	· · · · · · · · · · · · · · · · · · ·		
19	•		
20 21	Milwaukee, Wisconsin, this 11th day of July, 2024.		
21			
22	Inila Low burger 1088		
	ANITA KORNBURGER, RPR - Notary Public		
23	-		
	My commission expires May 24, 2025.		
24			
25			

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> Golkow Technologies, A Veritext Division

Federal Rules of Civil Procedure Rule 30

- (e) Review By the Witness; Changes.
- (1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:
- (A) to review the transcript or recording; and
- (B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.
- (2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1,

2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES

OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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